VOL. 24, NO. 4 APRIL 1969

Food Drug Cosmetic Law JOURNAL

Concluding Papers Presented at the 1969 Annual Meeting of the New York State Bar Association Section on Food, Drug and Cosmetic Law

A COMMERCE CLEARING HOUSE PUBLICATION
PUBLISHED IN ASSOCIATION WITH THE FOOD AND DRUG LAW INSTITUTE, INC.

THE EDITORIAL POLICY of this JOURNAL is to record the progress of the law in the field of food, drugs and cosmetics, and to provide a constructive discussion of it, according to the highest professional standards. The FOOD DRUG COSMETIC LAW JOURNAL is the only forum for current discussion of such law and it renders an important public service, for it is an invaluable means (1) to create a better knowledge and understanding of food, drug and cosmetic law, (2) to promote its due operation and development and thus (3) to effectuate its great remedial purposes. In short: While this law receives normal legal, administrative and judicial consideration, there remains a basic need for its appropriate study as a fundamental law of the land; the JOURNAL is designed to satisfy that need. The editorial policy also is to allow frank discussion of food-drug-cosmetic issues. The views stated are those of the contributors and not necessarily those of the publishers. On this basis, contributions and comments are invited.

The FOOD DRUG COSMETIC LAW JOURNAL is published monthly by Commerce Clearing House, Inc. Subscription price: 1 year, $20; single copies, $2. Editorial and business offices, 4025 W. Peterson Ave., Chicago, Ill. 60646. Printed in United States of America.

April, 1969
Volume 24 • Number 4

Second-class postage paid at Chicago, Illinois and at additional mailing offices.

FOOD DRUG COSMETIC LAW JOURNAL

Table of Contents . . . . . April, 1969

Page

Reports to the Reader 163

Product Liability—1968 ..... William J. Condon 164

Fair Packaging and the Informed Customer ..... Everette MacIntyre 173

International Food Law Developments in the Past Decade ..... Julius G. Zimmerman 184

Authoritative Effect of FDA Regulations ..... William F. Cody 195

Intensified Inspections—A Rule of Reasonableness ..... Vincent A. Kleinfeld 210

VOLUME 24 NUMBER 4

FOOD DRUG COSMETIC LAW JOURNAL

Editorial Advisory Board

REPORTS

TO THE READER

Twenty-Fourth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association.—The concluding papers presented at the meeting are featured in this issue of the JOURNAL. Previous papers were published in the March issue.

In his article, "Product Liability—1968," beginning on page 164, *William J. Condon* discusses several cases of product liability and compares the decisions of the courts. He includes statements of judges concerning the movement toward "social engineering to socialize losses." Mr. Condon concludes his article with a list of product liability cases for 1968.

Everette MacIntyre, a Commissioner of the FTC, in "Fair Packaging and the Informed Consumer," which starts on page 173, attempts to simplify the technical concept of the Fair Packaging and Labeling Act. He defines and develops specific sections of the Act and explains the effect that organizations such as the FDA and the FTC have upon it. Mr. MacIntyre believes the rationale behind the FPLA to be the sovereignty of the consumer.

Julius G. Zimmerman, a New York City attorney for the Coca-Cola Corporation, discusses "International Food Law Developments in the Past Decade." He summarizes the major trends of development in food law and cites specific legislation enacted by countries in order to achieve their ultimate goals: The establishment of a "harmonization" of international food laws and the assurance of an easy exchange of food supplies throughout the world. The article begins on page 184.

Authoritative Effect of FDA Regulations.—In the article beginning on page 195, *William F. Cody,* a New York attorney for Corn Products Co., discusses the use of the terms "legislative" and "interpretive" to classify regulations with respect to authoritative effect and the extent to which they are subject to judicial review. Mr. Cody discusses recent judicial pronouncements which suggest the "force of law" concept as being an intrinsic element of the Food and Drug Administration's rule-making authority, comparing the spectrum of such authority to that of the Federal Trade Commission. (Other papers delivered at the 91st annual meeting of the American Bar Association were published in the September and October, 1968, issues of the JOURNAL.)

Intensified Inspections—A Rule of Reasonableness.—In the light of past decisions of the Supreme Court in cases of unwarranted search, *Vincent A. Kleinfeld,* in the article beginning on page 210, examines FDA's new Intensified Drug Inspection Program (IDIP). He stresses the necessity for reasonableness in the exercise of authority, and suggests that industry may reserve the right of permission. Mr. Kleinfeld is a member of the District of Columbia Bar.

Vol. 24, No. 4 April, 1969

Food·Drug·Cosmetic Law
Journal

Product Liability—1968

By WILLIAM J. CONDON

The Following Article and the Two Succeeding Articles Were Presented at the Twenty-Fourth Annual Meeting of the Section on Food, Drug and Cosmetic Law of the New York State Bar Association, at the New York Hilton Hotel on January 28, 1969. Mr. Condon Is an Attorney with Condon and McMurray, New York City, New York.

PIERCING THE FRONTIERS of strict liability continues to be the primary emphasis in the product liability area. The majority of states have adopted the doctrine; some remain uncommitted. Wisconsin took the plunge just about a year ago in a case which is interesting for a number of reasons. The first of these lies in the fact situation. Very early on New Year's morning 1964, Donald Dippel was a patron in Tony Sciano's tavern. At the request and with the consent of Tony's agent, Donald and two friends undertook to move a large coin-operated pool table to a position where it could be used. As this was being accomplished, the front leg assembly of the table collapsed and separated Donald from two toes. Donald asked the Wisconsin Court to put its blessing on his action for breach of implied warranty against the distributor of the machine. This the Court refused to do on the ground that such an action will not lie in the absence of privity of contract.

However, the Court went on to say that it was time for Wisconsin to adopt the doctrine of strict liability in tort. A reading of the opinion suggests that this concept may be somewhat different in Wisconsin than it is generally understood elsewhere. Whether the difference will be significant in proving a plaintiff's case remains to be seen. It is almost certain to have a bearing on damages. Wisconsin has a comparative negligence statute which, in essence, provides that plaintiff's recovery will not be barred by contributory negligence unless the negligence of the plaintiff is at least equal to that of the

defendant, but his recovery will be diminished in proportion to the amount of negligence attributable to him. In an obvious effort to guarantee that this statute would be applicable to strict liability cases, the Court declared that in Wisconsin, strict liability is negligence per se. (*Dippel v. Sciano,* CCH PRODUCTS LIABILITY REPORTS ¶ 5897.)

Intended Use of Product

One of the important issues in a strict liability case is whether the harm of which plaintiff complains was incurred during an intended use of the product. The reason is that the product claimed to be defective is not unreasonably dangerous if the alleged defect would not cause injury during the course of a use for which the product was intended. Like many another legal proposition, the application of the principle is not as simple as its statement. The first question which immediately comes to mind is "What is meant by intended use?"

An example of this type of problem can be found in the case of *Olsen v. Royal Metals Corporation,* CCH PRODUCTS LIABILITY REPORTS ¶ 5896. Plaintiff was a nurse whose Achilles' tendon was severed when it was struck by the sharp crossbar of a hospital bed which was being used to move a patient from one room to another in a hospital. Plaintiff was assisting two doctors at the time and was positioned in front of the bed. Plaintiff's complaint alleging a defective design of the bed had been dismissed by the District Court for want of privity of contract. Inasmuch as Texas had abolished privity in all products cases in the period intervening between trial and appeal, the Court of Appeals for the Fifth Circuit reversed. In so doing, however, the Court considered it prudent to make several comments concerning the concept of defective design. It first pointed out that, since many products have both utility and danger, the initial question is whether the bed utilizing this type of crossbar is so dangerous that a reasonable man would not sell it if he knew of the risks involved. Whether the seller has knowledge of the risks involved is inextricably related to the question of intended use. A manufacturer has a right to expect that his product will be used in the normal and customary fashion. Here, the bed in question was sold as part of a hospital suite and there was substantial evidence that it was not intended for use in conveying patients from room to room in hospitals. It was much less expensive than the stretcher type bed, designed for that purpose, and the difference in design would have avoided the injury. However, there was also evidence

that beds of the type involved in this case were used for the purpose of moving patients about, not only in this hospital but in others, and that this fact was well known to the defendant. On all the facts, the Court concluded that whether or not the injury occurred during an intended use was one which should properly be left for the jury.

Duty to Warn

A second area which poses interesting problems and produces, at times, startling results involves the so-called duty to warn. Cases in this area deal with products which are properly manufactured, function as intended and are not in any sense defective. However, because of their nature, they contain inherent dangers giving rise to a duty to warn thereof. Again, the application of the duty to warn is sometimes very difficult. For example, in the case of *Rumsey v. Freeway Manor Minimax,* the product involved was an insecticide containing thallium. The action was brought to recover for the death of a three-year-old child who ingested some of this product. The product was labeled with a skull and crossbones and with the word "poison" written thereon in three places and otherwise complied with the requirements of the Federal Insecticide, Fungicide and Rodenticide Act. In accordance with the regulations promulgated under that statute, defendant had indicated that the antidote for this product was warm salt water. This is accurate in a loose use of the word "antidote" but not accurate in a technical scientific sense, because there actually is no specific antidote for thallium poisoning.

In these circumstances, there was a common law duty to warn of the full extent of the danger and the failure to state that there was no antidote for this particular poison constituted a breach of that duty. The Court went on to say that the labeling standards under the federal act were merely minimum standards and compliance therewith only evidence on the issue of negligence.

Another startling application of the duty to warn is to be found in the case of *Davis v. Wyeth Laboratories, Inc.* Plaintiff was a 39-year-old man who developed paralytic polio allegedly as the result of taking Type III Sabin oral polio vaccine at a mass immunization clinic conducted by a local medical society. All the material information in the possession of defendant manufacturer was transmitted to the medical society, including an indication that the risk of contracting polio through the ingestion of the vaccine for a person of plaintiff's age and circumstances was not significantly less than his risk of contracting the disease without the vaccine. The facts are many and

complex, and need not be repeated here. What is important is that the United States Court of Appeals for the Ninth Circuit held that the manufacturer of the vaccine was under a duty to warn the consumer himself of the risks involved and that its failure to give such a warning rendered the vaccine unreasonably dangerous and strict liability attached. An entire dissertation could be written on both the legal and public policy implications of this decision. The third case in this series involves a combination of the two concepts of duty to warn and intended use. In *Chandler v. Hunt Food and Industries, Inc.*, plaintiff purchased a bottle of cooking oil manufactured by defendant. She used a portion of it in a skillet to prepare french fried potatoes. When she was finished, she poured the used oil back into the bottle and replaced the cap. As she was carrying the bottle back to a storage cabinet it burst and she suffered rather severe burns from the hot oil. The thrust of plaintiff's complaint was that defendant violated a duty to give instructions for reuse of the oil and to warn that harm might follow from a failure to observe those instructions. The Court held that there is no duty to warn of a mere possibility of injury resulting from plaintiff's use of the product unless it can be shown that a substantial risk of explosion is present as well as that the particular use is expectable. Since plaintiff's complaint failed to allege that a substantial risk of explosion is present in defendant's product and that plaintiff's conduct was within the concept of the intended use, it did not state a cause of action.

It has become increasingly clear that, under whatever name it may be called, assumption of risk is a defense to a strict liability action. We have a rather unusual application in the case of *Bronson v. Club Comanche, Inc.* Plaintiff suffered a rather severe case of "ciguatera fish poisoning" as a result of eating native fish in defendant's restaurant in the Virgin Islands. The Court held that since plaintiff had lived in the area for a number of years and was aware that occasionally persons in that area do encounter this illness from eating fresh fish, she assumed the risk when she ate the meal in question and defendant was not liable.

Manifestation of Damages

Sometimes the most interesting and unexpected aspect of product liability cases is to be found in the particular manifestation of damage to the plaintiff. I would like to call your attention to two such cases. In the first of these, plaintiff ate a portion of bearing grease in a sandwich. Plaintiff had the mistaken impression that the grease

was rat excreta which caused her, for several months thereafter, to "see" rats and mice running around dishes and food and on the bedclothes. She was even able to describe how she tried to shake them off the bed on awakening and could hear them hit the floor. (*Finocchiaro v. Ward Baking Company.*)

If anything, the emotional reaction in the second case was even worse. Evelyn Holden purchased a white swim suit from defendant and she wore it for the first and only time on "family night" at her local pool. Her claim was that once the bathing suit became wet it was as transparent as cellophane, thus causing her untold humiliation, anguish and embarrassment. This, in itself, certainly should have been damage enough. But her damage continues, for she tells us that every time she goes to a party or to a picnic, somebody says "Let's turn the hose on Evelyn." Surely one can't but sympathize with these two most unfortunate ladies. (*Holden v. Kayser Roth Corp.*, CCH PRODUCTS LIABILITY REPORTS, ¶ 5986.)

There is no end to the type of damage that one might recover for defective products. Let me show you an example. Dr. George Thomas is a big game hunter. He has successfully hunted and shot grizzly bear, rhinoceros, leopard, moose, wild goat and other big game. In 1964 he purchased a Model 70 Supergrade Rifle manufactured by defendant and nationally advertised in publications, radio and television as a big game rifle. George went to India, hired a safari and set off in search of a Bengal tiger. On the fourth day of the safari he found his prey, the safety mechanism on the gun failed to work, the gun didn't go off and George lost his tiger. In his action against the manufacturer, the Court held that he had stated a good cause of action for express warranty and he has a right to attempt to prove the damage which he has suffered as a result thereof. (*Thomas v. Olin Mathieson Chemical Corporation*, CCH PRODUCTS LIABILITY REPORTS ¶ 5876.)

Conclusion

By way of a peroration I should like to quote to you three disparate but somehow connected statements. The first is by Justice Roberts of the Supreme Court of Pennsylvania, writing the opinion in a case involving a factory employee who put his hand into a glass-breaking machine while it was in operation. (*Bartkewich v. Billinger*, CCH PRODUCTS LIABILITY REPORTS ¶ 6075.) Justice Roberts said "We hardly believe it is any more necessary to tell an experienced factory worker that he should not put his hand into a machine

that is at that moment breaking glass than it would be necessary to tell a zookeeper to keep his head out of a hippopotamus' mouth."

The second is the language of Judge Osborn of the Court of Appeals of Kentucky dissenting in the case of *Post v. American Cleaning Equipment Corporation,* CCH PRODUCTS LIABILITY REPORTS ¶ 6063. The majority had found liability on the part of an industrial vacuum cleaner manufacturer to an experienced factory employee who was injured when the machine disintegrated upon being connected to a 220 volt line. The machine had a plate indicating that it should be operated on 115 volts and the lines in the factory were clearly marked with their voltage. The majority felt that the manufacturer had an obligation to warn of the dire consequences of using 220 volts. In his dissent Judge Osborn said:

> This case represents another step down the path of socializing losses that was started in *Dealers Transport Company v. Battery Distributing Co.*, Ky., 402 S.W. 2d 441. My opinion of this sashay is fully set out in a dissent in *Kroger Co. v. Bowman,* [CCH PRODUCTS LIABILITY REPORTS ¶ 5695] Ky., 441 S.W. 2d 339. The pseudo-legal jargon in which the opinion is couched is so vaporous that to attempt to attack it with legal principles would be like fighting the ocean with a sieve.
>
> The opinion contains one blatant untruth which requires some comment. It states, "If the dour consequences of using 220 D.C. had been forcefully and adequately posted—the appellee would prevail as a matter of law." It is my opinion it would have made no difference if the lettering had been ten feet tall and in flashing strobe lights. The result would have been the same. This opinion is the result of the doctrine of absolute liability without regard to negligence which has been imposed upon manufacturers of commercial articles. Its proponents seek to conceal the fact with the use of legal jargon in a pretense toward applying legal principles. I believe we should clear the air and call the movement what it is—social engineering to socialize losses.

Finally, let me repeat a quote which has already been seen in the Wall Street Journal of December 30, 1968 from an address by Frederick A. Fielder, president of CF&I Steel Corp. Mr. Fielder says:

> I can envision a subpoena being served on Mother Nature some time in the not too distant future asking her to defend herself against a products liability claim that might arise from improper raw materials on this earth being used in a product that eventually failed or worked improperly.
>
> Hopefully, that case would reach the highest court of all and be adjudicated in the manner it deserves. If not, we might just as well fold up our businesses, join the products liability plaintiffs on the other side of the bar and pray that there's enough cash remaining to be divided amongst ourselves so we can rightfully enjoy our remaining non-productive years in the manner we so richly deserve.

Further affiant saith not.

PRODUCT LIABILITY CASES FOR 1968

The list of cases for 1968, grouped according to classification, is as follows:

FOREIGN SUBSTANCE AND CONTAMINATED FOOD CASES

Wentzel v. Berliner, CCH PRODUCTS LIABILITY REPORTS ¶ 5883 (D. C. App., Fla.)

McCauley v. Manda Bros. Provision Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5893 (La. Ct. App.). Affirmed ¶ 6014 (La.)

Cassano v. Pilgreen's, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5921 (Ga. Ct. App.)

John Morrell & Co. v. Schultz, CCH PRODUCTS LIABILITY REPORTS ¶ 5948 (Miss.)

Falfurrias Creamery Co. v. Sanders, CCH PRODUCTS LIABILITY REPORTS ¶ 5959 (Tex. Ct. Civ. App.)

Finocchiaro v. Ward Baking Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5993 (R. I.)

Bronson v. Club Comanche, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6064 (Dist. Ct. of the Virgin Islands)

FOREIGN SUBSTANCE BEVERAGE CASES

Perez v. Glens Falls Coca-Cola Bottling Co., CCH PRODUCTS LIABILITY REPORTS ¶ 6023 (N. Y. App. Div.)

Neubauer v. Coca-Cola Bottling Company of Chicago. CCH PRODUCTS LIABILITY REPORTS ¶ 6035 (Ill. App.)

Harrison v. Canada Dry Corporation, CCH PRODUCTS LIABILITY REPORTS ¶ 6050 (D. C. Ct. App.)

Jackson v. Cushing Coca-Cola Bottling Company, CCH PRODUCTS LIABILITY REPORTS ¶ 6051 (Okla.)

BURSTING BEVERAGE BOTTLE CASES

The Kroger Company v. Goodhue, CCH PRODUCTS LIABILITY REPORTS ¶ 5906 (Ala.)

Wiley v. J. Weingarten, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5954 (La. Ct. App.)

Read v. Safeway Stores, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6044 (Cal. Ct. App.)

Beck v. Royal Crown Bottling Company, CCH PRODUCTS LIABILITY REPORTS ¶ 6074 (Tex. Ct. Civ. App.)

Levin v. Walter Kidde & Company, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6090 (Ct. App. Md.)

DRUG CASES

Lewis v. Geisinger Medical Center, CCH PRODUCTS LIABILITY REPORTS ¶ 5882. (Ct. of Common Pleas, Pa.)

Bine v. Sterling Drug, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5890 (Mo.)

Butler v. The Travelers Insurance Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5894 (La. Ct. App.)

Davis v. Wyeth Laboratories, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5908 (U. S. C. A.-9)

Atkins v. Hartford Accident & Indemnity Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5927 (Mich. Ct. App.)

Cheney v. Syntex Laboratories, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5938 (U. S. D. C., N. D. Ga.)

Shivers v. Good Shepherd Hospital, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5941 (Tex. Ct. Civ. App.)

Friedman v. Peoples Service Drug Stores, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5958 (Va.)

Tinnerholm v. Parke Davis & Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5994 (U. S. C. A.-2)

Herman v. Smith, Kline and French Laboratories, CCH PRODUCTS LIABILITY REPORTS ¶ 6066 (U. S. D. C., E. D. Wisc.)

Potter v. Krown Drugs, CCH PRODUCTS LIABILITY REPORTS ¶ 6085 (La. Ct. App.)

COSMETIC CASES

Perma-Strate Company, Inc. v. Gemus, CCH PRODUCTS LIABILITY REPORTS ¶ 5885 (Ct. App., Tenn.)

Hutchinson v. Revlon Corp. of California, CCH PRODUCTS LIABILITY REPORTS ¶ 5887 (Cal. Ct. App.)

Harris v. Belton, CCH PRODUCTS LIABILITY REPORTS ¶ 5946 (Calif. Ct. App.)

Procter & Gamble Mfg. Co. v. Langley, CCH PRODUCTS LIABILITY REPORTS ¶ 5960 (Tex. Ct. Civ. App.)

Newmark v. Gimbel's Incorporated, CCH PRODUCTS LIABILITY REPORTS ¶ 6041 (N. J. Super. Ct., App. Div.)

DEFECTIVE CONTAINER CASES

Coca-Cola Bottling Company of Houston v. Hobart, CCH PRODUCTS LIABILITY REPORTS ¶ 5907 (Tex. Ct. of Civ. App.)

Chandler v. Hunt Food and Industries, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 5969 (Tenn.)

Webb v. Zern, CCH PRODUCTS LIABILITY REPORTS ¶ 5975 (Pa. Ct. Common Pleas)

Elliott v. Alpac Corporation, CCH PRODUCTS LIABILITY REPORTS ¶ 5999 (U. S. C. A.-9)

Jankelle v. Bishop Industries, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6011 (Mass.)

Richard v. H. P. Hood & Sons, Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6025 (R. I.)

San Antonio v. Warwick Club Ginger Ale Co., Inc., CCH PRODUCTS LIABILITY REPORTS ¶ 6097 (R. I.)

DEVICE CASES

Magrine v. Spector, CCH PRODUCTS LIABILITY REPORTS ¶ 5974, (N. J. Super. Ct., App. Div.)

ANIMAL FEED CASES

Leach v. Wiles, CCH PRODUCTS LIABILITY REPORTS ¶ 5895 (Ct. App. Tenn.)

Kassab v. Central Soya, CCH PRODUCTS LIABILITY REPORTS ¶ 6065 (Pa.)

ECONOMIC POISON CASES

Rumsey v. Freeway Manor Minimax, CCH PRODUCTS LIABILITY REPORTS ¶ 5905 (Tex. Ct. of Civ. App.)

Carney v. Barnett, CCH PRODUCTS LIABILITY REPORTS ¶ 5910 (U. S. D. C., E. D. Pa.)

California Chemical Co. v. Lovett, CCH PRODUCTS LIABILITY REPORTS ¶ 5942 (La. Ct. App.)

Mosesian v. Bagdasarian, CCH PRODUCTS LIABILITY REPORTS ¶ 5961 (Cal. Ct. App.)

Martin v. Plymouth Cordage Co., CCH PRODUCTS LIABILITY REPORTS ¶ 5966 (Fla. Dist. Ct. App.)

Hodges v. The Fuller Brush Company, CCH PRODUCTS LIABILITY REPORTS ¶ 5997 (R. I.)

Eaton Fruit Co. v. California Spray-Chemical Corp., CCH PRODUCTS LIABILITY REPORTS ¶ 6061 (Ariz.) **[The End]**

Fair Packaging and the Informed Consumer

By EVERETTE MacINTYRE

Mr. MacIntyre Is a Commissioner of the Federal Trade Commission.

IN MANY RESPECTS, the Fair Packaging and Labeling Act (FPLA) and the administrative regulations drafted pursuant thereto are technical and complex. However, the key to understanding the Act and its implementation is a relatively simple concept set forth in its preamble, namely, "informed consumers are essential to the fair and efficient functioning of a free market economy." Clearly, packages and their labels, in the Congressional view, have a role to play in providing the consumer with accurate information and in facilitating value comparisons. The provisions of the Act, supplementary administrative regulations, and enforcement activity under the statute should all be evaluated within the context of these goals.

The rationale behind FPLA and other statutes such as the Truth in Lending Act which are designed to inform the consumer is clear. "[I]f the consumer is unable to choose on an informed basis, then his dollar is wasted."[1] Once the information required by the Act is provided, it has been said it will "return consumers to their rightful place as all-powerful sovereigns of the retail market and restore (if it was ever really absent) vigorous competition."[2] Informational legislation of this nature is a new development in that it does not merely seek to prevent deception although that is important, but additionally makes a positive attempt to provide the consumer with the tools for more effective buying decisions. Clearly, the average housewife spending perhaps 30 seconds of shopping time per item[3] in the supermarket needs all the help she can get.

[1] President John F. Kennedy, Message to Congress, 108 Cong. Rec. 4167, 4263 (1962).

[2] "Consumer Legislation and the Poor," 76 *Yale Law Review* 745, 749 (1967).

[3] See footnote 2 at 768.

I might note in passing that consumer-information bills of this nature have been considered as having definite antitrust implications. In fact, Senator Hart, a proponent of S. 387, one of the earlier "Truth-in-Packaging" bills, conceived of this legislation as an antitrust measure and introduced it as an amendment to the Clayton Act.[4] Its antitrust objectives were summarized as follows:

> The bill seeks then:
>
> 1. To enhance the integrity of markets in order that they may more accurately direct the productive activities of the economy.
>
> 2. To promote sound and effective competition by eliminating unfair competition in packaging and unfair or deceptive acts or packaging practices in commerce.
>
> 3. To assure equality of competitive opportunity for all efficient producers and distributors. Small businesses are especially vulnerable to irrationality in the marketplace. Because of its limited resources, the small business has a vital need for competitive standards that permit the focusing of attention on price and quality.
>
> 4. To promote effective price competition by minimizing the capacity of packaging to confuse or deceive the buyer and by permitting buyers to buy more intelligently and more rationally.
>
> 5. To make it more likely that profits will be channeled to the more efficient producer.
>
> 6. To assist the vast majority of honest businessmen by upgrading the economic value of fair packaging and labeling practices.
>
> 7. To increase the effective spending power of the average family (which spends $63 billion yearly, or approximately one-quarter of its income on products covered in this bill), by reducing needless waste in market basket expenditure.[5]

As a former Staff Director and General Counsel of the House Select Committee on Small Business, I must admit an interest in the suggestion that promoting rational purchasing decisions will also foster the competitive opportunities of small business. Although the Fair Packaging and Labeling Act of 1966 was not enacted as an antitrust law, the objectives of the earlier Truth-in-Packaging bill, S. 387, are, in my view, entirely consistent with the Statute now on the books. They deserve consideration both by industry and the enforcement agencies.

The first and crucial step in implementing the Act is the promulgation of the administrative regulations required and authorized by the Statute. It is the crucial step because Congress left the writing in of the Statute's details to the responsible administrative agencies.[6]

---

[4] "Truth-in-Packaging," Report of the Subcommittee on Antitrust and Monopoly of the Committee on the Judiciary, U. S. Senate, Committee Print. 3, 88th Cong. 2d Sess. (1964).

[5] See footnote 4 at 3, 4.

[6] Hart, "Truth-in-Packaging Revisited," 22 FOOD DRUG COSMETIC LAW JOURNAL 317 (June 1967).

"[T]he need for flexibility and specific expertise demanded this approach. Congress is not equipped to write detailed specifications for hundreds of product lines. Nor does freezing this kind of detail into a statute make much sense."[7] Under the circumstances, the effectiveness of the Act clearly depends on how the administrative agencies respond to the legislative mandate.[8]

In assessing the role of the Federal Trade Commission, it should be kept in mind that other governmental agencies also have their part to play in administering the Act. For example, the Food and Drug Administration enforces the Act insofar as it applies to food, drugs, cosmetics and devices, while the Federal Trade Commission is responsible for any other consumer commodities. This division of jurisdiction resulted from the desire to cause minimal disruption to the lines of authority developed by each agency in its area of responsibility, and to take advantage of the expertise that each had developed in its own field.[9] The third Federal Agency with responsibilities under FPLA is the Department of Commerce. Its functions under the Act are not regulatory, but to institute voluntary measures in cooperation with industry and consumers to achieve the objectives of the Statute.[10] State authorities, it is hoped, will take action to promote uniformity in State and Federal Regulation of consumer commodities. With three Federal Agencies responsible for implementation of FPLA, the need for coordination between them is clear, if burdensome conflicts are obviated and the Statute's objectives achieved.

Three Classes of Regulations

Administrative rule-making under FPLA falls into three classes, mandatory, discretionary and voluntary regulations. The Food and Drug Administration (FDA) and the Federal Trade Commission (FTC) each within its own area of responsibility have the task of promulgating appropriate mandatory and discretionary rules pursuant to Sections 4 and 5 of the Statute. The first order of business for this agency of necessity has been the issuance of mandatory regulations under Section 4 of the Statute, the labeling provision of the Act. Here the final regulations of the Commission, published in the Federal Register, March 19, 1968, are designed to achieve the legislative goals by ensuring that the labels on consumer products will supply

[7] See footnote 6.
[8] See footnote 6.
[9] Senate Report, see footnote 4 at 14.
[10] Hollomon, "The Role of the Department of Commerce," 22 FOOD DRUG COSMETIC LAW JOURNAL 327 (June, 1967).

meaningful information relating to identity of the product, name and place of business of the manufacturer, packer or distributor and net quantity of contents. The regulations pursuant to Section 4 are of course "mandatory" because in this area Congress has made the determination that the necessity for remedial regulation of this nature exists. The regulatory agencies, therefore, have discretion in promulgating such rules only in the sense that they are to seek the most practical way of ensuring that the consumer is provided with the information required by Section 4 of FPLA. The Commission and FDA in promulgating the mandatory regulations have coordinated their programs to ensure as much uniformity as possible. The liaison between the two agencies has been successful and when minor differences in the regulations exist, this is primarily due to the differences of the products within each agency's jurisdiction.

Objections to the mandatory rules promulgated by the Commission have been filed. Gratifyingly, while they indicate some differences between industry members and the Commission on matters of detail, they do not suggest that industry is using the provisions for filing objections in an attempt to seek an administrative repeal of significant portions of FPLA. This is important. Because of limited funds, time and manpower, this agency must, to the greatest extent possible, seek to implement the Act in a context of cooperation rather than in an adversary atmosphere.

Since the agencies' discretion in determining whether Section 4 regulations should issue is sharply circumscribed, it is unlikely that their promulgation will lead to fundamental conflicts between the Commission and industry. More difficult and interesting problems will undoubtedly arise in connection with the Commission's exercise of discretionary rule-making power under Section 5(c) of FPLA, a function which to date has not yet been exercised. That section authorizes regulation to: standardize package size characterizations such as "giant size"; control use of price savings claims on labels, for example "cents off"; require listing of ingredients by order of decreasing predominance; and prohibit non-functional slack-fill of packages *provided* that the FTC or FDA find such rules are necessary to prevent consumer deception or facilitate value comparisons. Obviously, the requirement that the Commission make a finding of necessity before such rules issue under Section 5 presents a greater opportunity for conflict than Section 4 regulations where Congress has already determined that action must be taken.

"Price" or "Value"?

As noted by other commentators, one of the more intricate problems under FPLA and one which will undoubtedly come into focus in the case of discretionary regulations is the statutory meaning of the phrase to "facilitate value comparison." The Act itself does not specifically define the term and the legislative history appears to be in conflict, a dispute frequently noted in comments on the Act in the last two years.[11] The Senate's Truth-in-Packaging bill declared that it is the policy of the United States to assist consumers by facilitating price comparisons. The House version substituted the word "value" for "price" and this change was incorporated in the final bill. Senator Hart was pleased with this revision because it broadened Congressional policy to include quality comparisons, which he viewed as having vastly greater implications than the more limited concept of price. This, he felt, opened the door to consideration of legislation for grade labeling and government testing of consumer products. In Senator Hart's view, the House amendment was clear and unambiguous on its face. Changing the word "price" to "value" added the element of quality to the policy statement. Congressman Gilligan, the author of the House amendment, on the other hand, stated the purpose of the substitution of the term "value" for "price" was designed to ensure that the administrative agencies responsible for enforcement of the Act would not exercise their powers for the sole purpose of "facilitating a mathematical computation; that is, a price comparison in the supermarket aisle." In his view, price was only one element in the consumers' value decision; other factors of greater or equal importance are the products' performance, the convenience of the package, and suitability of the size or quantity of the product in satisfying a consumer's personal desire and need; Representative Gilligan viewed "value" as a highly subjective concept.[12]

Senator Hart relied on the conferees' report stating that the House version substituting "value" for "price" simply intended to make it clear that the term "value comparison" is broader than the concept of "price comparison" and includes the latter within the former as a very important factor in making a value comparison.[13]

[11] See, for example, Kennedy, "Now That The Fair Packaging and Labeling Act is Law," 21 FOOD DRUG COSMETIC LAW JOURNAL 632, 643-644 (December 1966).

[12] Hart, see footnote 6 at 320.

[13] See footnote 6 at 321.

Evidently, in response to Representative Gilligan, Senator Hart wished to make it clear that the term "value" is not to be construed as precluding regulations designed to facilitate price comparisons.

The term "value comparison" might mean a number of things. It might mean that the Commission under its discretionary regulations is to facilitate value comparisons by going into elements in addition to price such as performance, convenience, etc. Representative Gilligan's statement might be construed as implying that such elements should take precedence over price in a consideration of value comparison. Senator Hart, on the other hand, as already noted, made it clear that while value comparison is broader than the concept of price comparison, it definitely includes the latter within the former. Perhaps the Commission should seek to facilitate price comparisons and also if possible take into consideration other elements of importance to the consumer in his purchasing decisions. In any event, it may turn out that the Commission, under Section 5(c) of the Act, will emphasize price in considering value comparison because of the practicalities of the situation. The Commission is not set up to do the job at least on a large scale of evaluating such things as product performance or grade labeling. Senator Hart seemed to recognize this when he stated that inclusion of the term "value comparison" opened the door to consideration of legislation providing for grade labeling and government testing of consumer products. This implies that additional machinery would have to be set up in addition to FPLA if such objectives are to be achieved. Certainly, action to facilitate price comparisons, to a considerable degree already required by Section 4 of the Act, is clearly within the purview of the Statute and would not require additional elaborate machinery to carry into effect.

I might also note at this juncture, that there may be pitfalls in the attempt to facilitate value comparison by rules relating to product performance, quality, etc. If certain competitors should be favored by virtue of such action, considerable care would have to be exercised that such regulations do not erect new barriers to competition. Consider, for example, the warning last November by the Assistant Attorney General in Charge of the Antitrust Division that private standards under Section 5(d) of FPLA, relating to undue proliferation of weights and measures based upon the products or capabilities of a dominant group of manufacturers, could arbitrarily handicap smaller competitors who might find compliance difficult and that care

should be taken to avoid standards which may impede innovation and new entry.[14]

"Cents-Off"

A number of problems falling within the scope of Section 5(c) of FPLA are now under consideration at the staff level, including the "cents-off" question, slack-fill, and the possibility of requiring the listing of ingredients of certain classes of commodities in order of decreasing importance. At the moment the staff is concentrating on the "cents-off" problem.[15] By switching the "cents-off" problem from the mandatory to the discretionary section, Congress has handed the regulatory agencies a volatile issue. It is doubtful that a perusal of the legislative history shows a question generating more heat in the discussions and hearings leading up to passage of the Act. The Senate report on S. 387 condemned "cents-off" as inherently deceptive because the manufacturer has no influence or control over the prices set by the retailer. It charged "the manufacturer is promising a retail price advantage on which he cannot deliver. He is, in effect, making a promise to the consumer on which the consumer cannot rely."[16] Those opposing proposals for outlawing the practice replied that "cents-off" has a legitimate place in contemporary competition as an effective means by which manufacturers may make the consumer aware of their products and to induce changes in buying habits. They extolled "cents-off" as a genuine form of price competition.[17]

Pricing claims of this nature are within the scope of Section 5(c)(2) of the Statute. The House report on the bill makes it clear that in the House's view, the Act authorized the agencies to regulate but not prohibit the use of such promotions. The Senate report, on the other hand, seems to indicate that the practice may be prohibited if it cannot be regulated so as to ensure that it will be non-deceptive.[18] The question before the Commission then is, assuming the need for regulation exists, what will be the primary issues governing regula-

[14] Assistant Attorney General Zimmerman's Letter to Commerce Department.

[15] Earl Johnson, "The Law and Package Labeling," before the American Management Association, December 4, 1968.

[16] Senate Report, see footnote 4 at 17.

[17] See footnote at 54, 55.

[18] H. Rep. No. 2076, 89th Cong. 2d Sess. 7 (1966); S. Rep. No. 1186, 89th Cong. 2d Sess. 6 (1966).

tions designed to ensure non-deceptive use of the "cents-off" regulations? At this point, I do not propose to offer any answers, but hope that a consideration of some of the relevant questions may be of help in clarifying the problem. Obviously, the prime issue is "cents-off" what? Does this representation mean "cents-off" the retailer's price, the manufacturer's price, the area price or an after-sale price? Obviously, the first determination which has to be made is what does "cents-off" mean to the consumer, or what is the pricing representation if the term is unqualified? If it is considered to be the retailer's own price, quite different considerations come into play than if it is viewed as a comparable value or area price representation. Conceivably, the problem could be solved by requiring those responsible for the "cents-off" label to specify precisely the nature of the price involved in the offer.

Assuming that the "cents-off" representation in fact refers to an area price, enforcement might prove quite difficult because establishing an area price under present procedures can be a difficult, complex and frustrating exercise.[19] On the other hand, if a "cents-off" representation is geared solely to the retailer's own price then the question of determining the claimed price savings would, of course, be greatly simplified.

An equally critical question is, are regulations necessary to ensure that "cents-off" savings are actually passed on to the consumer? If regulations make the manufacturer responsible for seeing that the "cents-off" are actually passed on by the retailer, the question arises how at the same time can such regulations avoid setting up a system of *de facto* resale price maintenance? Certain manufacturers appear to be addressing themselves to this problem. I have noted that in the case of some products, a coupon equivalent to the "cents-off" offer has been included in the package for redemption in the retail store.

Other obvious questions coming to mind in connection with "cents-off" are: Should regulations provide for an appropriate period preceding "cents-off" offers during which a customary selling price would be established? Should a maximum duration be fixed for "cents-off" promotions and should these regulations take into consideration the relationship between "cents-off" and other promotions

[19] See Revised Pricing Guides, 2 CCH TRADE REGULATION REPORTS ¶ 7897; *Revco D. S., Inc.*, FTC Docket No. 8576 (1965).

in the same period? Can a "cents-off" offer for a newly marketed product be legitimate under any circumstances? A complicating factor is that discretionary regulations under Section 5(c) are product line rules not intended to cover all consumer products within the scope of the Act. Every effort should be made, of course, to achieve consistency for discretionary regulations on subjects such as "cents-off," but it is not unlikely that the Commission will be faced with claims that different products require unique treatment in certain respects. The foregoing does not pretend to be an exhaustive catalog of the problems which will have to be faced, should such regulations be promulgated. Nevertheless, even this limited discussion compels the conclusion that workable practical solutions will require a great deal of hard work and thinking.

In addition to promulgating substantive regulations under the Act, the Commission and the Secretary of Health, Education and Welfare are also empowered to issue rules exempting certain consumer commodities from full compliance with the requirements of the Act where their application would either be impracticable or not necessary for the adequate protection of consumers. The exemption procedure is interwoven with the administrative function of amplifying and implementing the statutory definition of the term "consumer commodity" contained in Section 10 of the Act. The Commission initially determined that it would not be practical to promulgate a general definition of consumer commodities and the process of definition is now taking place largely under Section 5(b)'s exemption provisions. Judging from the number of requests for exemptions, ranging from mops to automobile parts,[20] the rulings thereon will have an undeniable impact on the scope of the Act. It is under the exemption procedures that the Commission may face some of the most crucial problems of enforcing the mandatory regulations.

In concluding my remarks, it may be pertinent to note that the experience of the Commission under the FTC Act requiring it to define unfair acts or deceptive acts and practices should stand it in good stead in exercising its functions under the FPLA. Under the FTC Act, the Commission had the duty "to discover and make explicit those unexpressed standards of fair dealing which the con-

[20] 2 CCH TRADE REGULATION REPORTS ¶ 7430.02 (1968).

science of the community may progressively develop" and its powers were not confined to those practices which were unlawful before it acted.[21] The phrase, unfair methods of competition, significantly did not, as the courts noted, admit of precise definition, but had to be reached by a gradual process of judicial inclusion and exclusion.[22] As a result, the Commission has gained expertise in the kind of analysis which should be helpful in framing the regulations necessary to prevent deception or to facilitate value comparison under FPLA. The objectives of the FTC and Packaging Acts are not far apart and to a considerable degree coincide.

It may not be amiss to point out at this time when the efficacy of the Commission's programs once more is being called into question that many of the concepts giving rise to the new consumer oriented legislation were developed under the broad mandate given this agency by the FTC Act in 1914. The Congressional hearings, such as those held by the Senate Antitrust Subcommittee, must, of course, be given the primary credit for creating the legislative impetus leading to the passage of FPLA. Nevertheless, the Commission's enforcement of Section 5 of the Federal Trade Commission Act and in particular after passage of the Wheeler-Lea Amendment has played a role in helping to lay the foundation for the enactment of such legislation by helping to articulate "those unexpressed standards of fair dealing which the conscience of the community may progressively develop." Commission adjudicative cases have articulated guidelines in the area of merchandising, marketing and advertising which have had the tendency of eroding the concept of *caveat emptor* and to establish the principle that the customer should have sufficient information to make rational buying decisions. For example, Commission cases have established the principle that impressions are the primary targets of the ad writers,[23] and that advertisements, although literally true, may be deceptive if they do not tell the whole truth.[24] Judicial precedent in Commission cases has held that those deserving protection by regulatory action are the trusting as well as the suspicious, the casual as well as the vigilant and the naive as well as the sophis-

[21] Learned Hand, Speaking for the Court in *FTC v. Standard Education Society*, 86 F. 2d 692, 696 (2nd Cir. 1936), modified 302 U. S. 112 (1937).

[22] *FTC v. Raladam Co.*, 283 U. S. 643, 648 (1931).

[23] *Stanley Laboratories, Inc., et al. v. FTC*, 138 F. 2d 388, 392 (9th Cir. 1943).

[24] *Maurice J. Feil, et al. v. FTC*, 285 F. 2d 879, 896 (9th Cir. 1960).

ticated.[25] Certainly, the Commission's guideline requiring affirmative disclosure of the applicable limitations of advertising, where silence on a material fact is deceptive in light of the claims actually made,[26] was a development helping to set the stage for informational legislation such as FPLA. These cases contributed their part in developing the concept of the consumer's "right to know" which lies at the heart of the new consumer legislation. Significantly, Section 11 of the Fair Packaging Act specifically states that the Act is not to be construed as repealing, invalidating or superseding among other statutes the Federal Trade Commission Act or any law defined therein as an antitrust statute. Clearly, while the Commission will proceed vigorously to implement the mandate of FPLA, it is not precluded from proceeding under Section 5 of the FTC Act against unfair acts and deceptive practices in this area which Congress may not have foreseen but which nevertheless require corrective action.

[The End]

FPLA REGULATIONS EFECTIVE DATE EXTENDED

The effective date of the packaging and labeling regulations for drugs, devices, and cosmetics originally issued by the Food and Drug Administration in January, 1968, to implement the Fair Packaging and Labeling Act has been extended to December 31, 1969. The regulations were to become effective on July 1, 1969.

One firm objected to the failure of the regulations to categorize, identify, and provide labeling guidance for "professional drugs and devices." According to the Commissioner of the FDA, these products are not covered by the FPLA because they are not "consumer commodities." Consequently, a public hearing was denied on this objection, and the regulation (§ 1.102d) under attack has been revised to clarify its limitations.

The FDA considered as insubstantial a trade association's objection to the cosmetic regulation requiring uniform type sizes for all packages of essentially the same size. Its request for a public hearing concerning permission to use smaller type for the net contents declaration on small cosmetic packages was denied.

Though the FDA found a stay in the effective date of the regulations unwarranted, an extension of time was granted in order to allow manufacturers, some of whom were unable to revise their labels while objections were pending, to comply with the Fair Packaging and Labeling Regulations.

FDA Order, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,342 and 21 CFR Part 1, ¶ 9911—9919 and 9937—9942.

---

[25] See *Colgate-Palmolive Co. et al.*, 59 FTC 1452, 1464 (1961), rev'd and remanded, 310 F. 2d 89 (1st Cir. 1962); final order, transfer binder 1961-1963, ¶ 16,403 (FTC 1963); rev'd 326 F. 2d 517 (1st Cir. 1963); rev'd 380 U. S. 374 (1965).

[26] See "Developments in the Law—Deceptive Advertising," 80 *Harvard Law Review* 1005, 1048-49 (1967); and *The J. B. Williams Co., Inc., et al. v. FTC*, 381 F. 2d 884 (6th Cir. 1967).

International Food Law Developments in the Past Decade

By JULIUS G. ZIMMERMAN

Mr. Zimmerman Is a New York City Attorney for The Coca-Cola Corporation.

EXACTLY TEN YEARS AGO I had the privilege of submitting to the Food, Drug and Cosmetic Law Section of the New York State Bar Association a report on the Progress of Foreign Food Laws during the previous decade.[1] At the occasion of such an anniversary one is tempted to repeat the former performance by submitting a comprehensive and detailed report on all that has happened during the last decade. That, however, would be a hopeless task in view of my time limitation and the sheer mass of factual information that would have to be reported. We live in an age of dramatic events and are used to dramatic headlines, and maybe the current developments in our field of interest can be appropriately described as an "explosion of food law." However, in order to retain the true perspective it would be more accurate to relate this descriptive term to the mid-century as a starting point. Therefore, I would rather try to summarize the main trends of the developments in the international field of food law and limit my specific comments on recent legislation on the national level to those items which have landmark significance.

By 1950 the chaos left in the wake of World War II was being gradually brought under control and being replaced by a post-war era of high pressure developments on a global scale which had a truly explosive force and revolutionized almost every aspect of the life of nations as well as the life of individuals. The most important factors affecting the subject of food and food law are, in my opinion:

[1] Zimmerman, "Progress of Foreign Food Laws" 14 FOOD DRUG COSMETIC LAW JOURNAL 189 (March, 1959).

1. The "population explosion" of the post-war era. The total population of the world was about 3 billion people in 1960, and the experts predict that it will reach 6 billion in the year 2000, and 13 billion in 2050, if the present trend continues unchecked;

2. The internal migration of people from rural areas to the industrial centers wherever they exist or are being newly created;

3. The development of modern rapid transportation facilities by surface, underground, and by air, and most recently by travel through space;

4. The development of the news media which transmit information to all parts of the world within seconds;

5. The electronic collection and processing of data by computer;

6. The developing of ultra-modern new packaging methods for foods;

7. The birth of many new sovereign nations as the result of the liquidation of the Colonial Era which increased the membership in the United Nations to 126; to this must be added a number of nations which are not members of the U. N. but some of which are members of the specialized agencies World Health Organization (WHO) and Food and Agriculture Organization (FAO). Many of these new nations and also of the old established nations have an insufficient food production and an uncontrolled growth of population;

8. The growing interest and awareness of the consumers in the field of nutrition and the concept of a balanced diet.

The combination of all these factors is putting the governments of all food producing countries under a relentless pressure to produce a much greater quantity of food for quick distribution to many more people over longer distances.

If we consider the status of food legislation in the various countries of the world at the turn of the mid-century, we find that most of it was obsolete or inadequate to cope with the modern age. That was even true of the food legislation in the United States which was based on the Food, Drug and Cosmetic Act of 1938 which was one of the most elaborate and modern bodies of food legislation in the world prior to World War II. The major impetus to modernizing the U. S. Food Law was provided by the hearings of the Delaney Committee on Food Additives which aroused world-wide interest and led to the Amendment of 1958, followed by the Color Additive Amendment of 1960, and the Fair Packaging and Labeling Act of 1966. Similar

developments took place abroad and culminated in the enactment of special legislation on Food Additives in Mexico[2] and Germany[3] in 1958, and a great volume of similar legislation in other countries in all parts of the world during the last decade. The "Modern Age" legislation was not limited to Food Additives even though they are responsible for the greatest share of it.

These recent developments brought about a substantial increase of government control over the manufacture, sale and distribution of prepackaged foods. Prior to 1950 there were still many countries whose food law consisted mainly of general rules prohibiting the manufacture and sale of harmful, adulterated or mislabeled foods, and an outright prohibition of the use of certain substances considered harmful per se and specfically listed in so-called negative lists. Under this system of "abuse" everything that is not harmful or in direct violation of a specific prohibition is permitted, with the government having the burden of proof concerning an alleged violation. Some other countries went to the other extreme and either required a prior license for every type of prepackaged food (that was and still is the case in many countries in Latin America), or followed the principle of "prohibition" according to which everything that is not specifically authorized is prohibited. Under such a system the burden of proof that there is no violation lies with the individual who is charged with it. The introduction of special and detailed rules on the use of the so-called "food additives" whose number is in the four digit bracket, changed the world-wide situation very considerably in favor of the system of "prohibition."

Modern Food Laws

The attempt to regulate the use of food additives in detail requires an ever-increasing volume of regulation. These modern regulations usually classify the additives into categories based on their functions, such as colors, preservatives, antioxidants, emulsifiers, foaming agents, etc., and then issue specific positive lists authorizing the use of each additive for certain individual categories of food products, with or without certain limitations.

---

[2] "Mexican Regulation on Food Additives" January 21, 1958, English translation of the text, 13 Food Drug Cosmetic Law Journal (June, 1958). Frisbie and Farias, "Health and Food Legislation in Mexico" 16 Food Drug Cosmetic Law Journal 537 (September, 1961).

[3] Jochmus, "The New German Law on Food Additives" December 21, 1968. 14 Food Drug Cosmetic Law Journal 431 (July, 1959). Zimmerman, "Germany—Regulations on Food Additives" 15 Food Drug Cosmetic Law Journal 280 (April, 1960).

Special attention has been given in recent years also to:

1. The regulation of the packaging of foods, including the chemical substances used in the manufacture of packages, and the standardization of container sizes;

2. The regulation of "dietetic" foods which are becoming increasingly popular with the "weight watchers."

3. The regulation of enriched, fortified and vitaminized foods the labeling of which usually contains nutritional claims;

4. The regulation of food labeling in general as the result of pressure of consumer organizations for more information.

During the last decade quite a few countries have modernized their food laws and the related laws along the lines mentioned above, and it is interesting to note that such developments are taking place in all parts of the world.

The United Kingdom, for instance, issued not less than 11 different Regulations on Food Additives alone between 1959 and 1967, and much of this type of legislation has also been promulgated on the European continent.

Spain deserves a special mention because it adopted on September 21, 1967, a comprehensive Food Code (Código Alimentario Español)[4] which consists of 38 chapters and covers all types of foods and beverages (alcoholic and nonalcoholic) and related items such as tobacco, packaging materials, fertilizers and pesticides.

On the other side of the globe Japan revised in 1957 its basic Food Sanitation Act of 1900 and authorized the Minister of Health to issue standards for food additives which was done on March 15, 1960.[5]

India revised its "Prevention of Food Adulteration Act of 1954" in 1962 and the Rules of 1955 in 1962, 1964 and 1966.

West Pakistan issued in 1965 a new Pure Food Ordinance and Rules.

In Latin America a very significant event of national food legislation took place in Brazil, which issued its first National Health

[4] Codigo Alimentario Espanol (Decreto 2484/1967), published as a separate volume by *Gaceta de Madrid* (Official Gazette of the Spanish Government).

[5] An English translation of these Standards was published by the Japan Food Hygiene Association. Oser, "Food Additives in Japan" 22 FOOD DRUG COSMETIC LAW JOURNAL 611 (November, 1967).

Code on January 21, 1961, and three days later a very comprehensive Regulation on Food Additives (Decree 50.040 of January 24, 1961, as amended). A unique feature of the Brazilian food labeling requirements is the use of a coding system (a combination of Roman and Arabic numerals) for the identification of the additives in the food. In 1967 Brazil also issued a National Food Code (Decree 209 of February 27, 1967) and a Regulation on Dietetic Foods (Decree 61149 of Aug. 9, 1967).

The complex nature of any comprehensive regulation of the use of food additives makes it imperative for the legislator to deal with it by way of administrative rule-making under a general enabling act which delegates this task to one or more government agencies. But even that method may be very cumbersome and time consuming, especially in countries where the law requires public hearings or provides for other safeguards against arbitrary rule-making, such as a judicial review. Furthermore, much of the rule-making in this field is based on scientific research which is never at a standstill and is usually responsible for the implementation or other amendments of previously approved lists of food additives, both positive and negative. On the other hand, the methods of scientific research and analysis used in a particular country and acceptable to the local government are far from uniform on a world-wide basis and are frequently not acceptable to the health authorities of other countries which accounts for many differences in the national food laws.

Another difficulty is created by the absence of a uniformly accepted world-wide legal terminology of many of the basic concepts and terms used in virtually all of the national food laws, such as "food," "ingredient," "food additive," "foreign substance" and the concepts of "natural" and "artificial." This is further complicated by the problem of translating such terms into other languages or finding a proper equivalent for them where a literal translation would be misleading.

All these complexities of modern food legislation make it imperative for all the countries of the world, and particularly the food producing countries, to establish and develop a close cooperation on an international scale in order to achieve a certain "harmonization" of the national food laws and to assure an easy exchange of food supplies which are fit for human consumption but frequently barred by technical obstacles connected with the rigidity or obsolescence of certain national food laws.

In several parts of the world certain groups of countries set up regional Common Markets or Free Trade Associations in order to make available to their people the economic advantages of larger trading areas. The European Economic Community (EEC) and the European Free Trade Association (EFTA) are already functioning in Europe as free trade areas. A similar set-up exists in Latin America with a Central-American Common Market (CACM) and a Latin-American Free Trade Association (LAFTA).

Harmonized Food Legislation

It is, of course, essential for a Common Market or a free trade area to have uniform or at least harmonized food legislation in order to assure the unhindered exchange of agricultural commodities and prepackaged food within the limits of the Community. As a matter of fact, however, such a harmonization of food laws is sometimes delayed because of internal political considerations and maneuvering. Thus, in the case of the EEC which was established by the Treaty of Rome in 1957 and which has a very elaborate procedural set-up for the harmonization of food laws,[6] the internal customs duties between its six member nations—France, Federal Republic Germany, Italy, The Netherland, Belgium and Luxemburg—have been eliminated, but the efforts to harmonize the food laws have so far produced only two "Directives" on Preservatives and one on Food Colors. A Directive is not directly applicable as a law in the member nations but merely obligates the individual governments to bring their national law in line with the Directive within a given period of time.

In the Western Hemisphere, the Central-American Common Market which was created by the Treaty of Managua in 1960 is already functioning very well as a Free Trade Area. It consists of the five republics, Guatemala, Honduras, Costa Rica, El Salvador and Nicaragua, with Panama as an associate member. All six republics have agreed in principle to adopt uniform food standards, and at their request for assistance the Pan American Sanitary Bureau (PASB)

[6] Adams and Karl, "Harmonization of National Food Laws under the Treaty System of the European Economic Community" 20 Food Drug Cosmetic Law Journal 357 (June, 1965). Van der Steur, "Developments in the EEC—Food Legislation" 20 Food Drug Cosmetic Law Journal 581 (October, 1965). Ventura, "The Common Market and Harmonization of the Food Laws" 21 Food Drug Cosmetic Law Journal 440 (September, 1966).

in Washington (the regional office of the World Health Organization) sponsored the drafting of such standards by delegating this task to Dr. Ariosto Büller Souto, Director of the Instituto Adolfo Lutz in São Paulo, Brazil, the largest Bromatological Institute and Laboratory in Latin America, which provided the staff and the technical assistance for this project. Dr. Büller Souto managed to complete this assignment before he died in 1968. The first three volumes, with 380 of these standards, were approved by the Health Ministers of the six republics and the text of these standards was published in Spanish by the PASB in Washington last year. However, to the best of my knowledge none of these standards has been so far legally promulgated by any of the six republics. The Standards are called "Normas Sanitarias" and are intended to be supplemented in due course by voluntary Standards of Quality to be drafted by an organization called Central American Research Institute for Industry (ICAITI). On the other hand, the Institute of Nutrition of Central America and Panama (INCAP) is to set up the necessary Laboratories for Food Control.[7]

I understand that the Central American Republics are contemplating joining LAFTA, which presently has nine member nations, namely Argentina, Brazil, Chile, Colombia, Ecuador, Mexico, Paraguay, Peru and Uruguay, and that LAFTA, in turn, is planning to become a Latin-American Common Market. The question remains open what is going to be done with respect to Common Food Standards for this larger trading area. The Inter-American Bar Association (IABA) put itself on record, in 1965, by recommending to the member nations of LAFTA adoption of the Latin-American Food Code as the sole legal instrument in this field. This complete volume of Food Standards under the title "Código Latinoamericano de Alimentos" was published in its first edition in 1960 and in its second edition in 1964. A third revised edition has been completed and will be submitted to the Latin-American Chemical Congress which meets in San José, Costa Rica, early in February, 1969. This organization was the original sponsor of the project at its meeting in Caracas in 1955 when it entrusted the well-known Argentine Health Official, Dr. Carlos A. Grace, with the task of drafting a set of Food Standards to serve as a model for all Latin America, which he did with the cooperation of

[7] Olszyna-Marzys, "Food and Drug Law in Central America and Panama" 23 FOOD DRUG COSMETIC LAW JOURNAL 253 (May, 1968).

food technologists from 16 Latin-American Republics. However, up to now only two countries have adopted the Latin-American Food Code in toto—Ecuador and Cuba—but several other countries have incorporated portions of it in their national food legislations. It had, in general, a considerable influence on food legislation throughout Latin America, but it remains to be seen how this problem of uniform food standards for Latin America will develop in the future, particularly if and when the world-wide Standards which are drafted by the FAO/WHO Codex Alimentarius Commission will be completed and begin to compete with the regional standards. Incidentally, the Food and Drug Law Committee of the Inter-American Bar Association is planning to put this topic of Uniform Food Standards for Latin America on the Agenda of its next meeting in Rio de Janeiro on June 24, 1969, during the XVI Conference of the IABA.

Let us now switch over to Europe and review briefly the FAO/WHO Codex Alimentarius set-up, the creation of which was undoubtedly the most important event during the last decade.

Codex Alimentarius

The Codex Alimentarius is a joint project of the FAO and the WHO. It was set up in 1962 to take over the European Food Code Organization of Dr. Hans Frenzel, the former Austrian Minister of Health, which had won the active support and participation of 19 European nations. However, the Codex Alimentarius project was meant from the start to develop Model Food Standards for world-wide application. The Codex Alimentarius Commission met for the first time in 1963 and since then every year except in 1967. As of March 1, 1968, at the end of the Fifth Session in Rome, the Commission had 52 member nations from all parts of the world and including the United States. The U. S. representative at the last Session was Mr. George R. Grange and the alternate delegate Robert F. Anderson, both of the U. S. Department of Agriculture. Our two official delegates were accompanied by 8 advisers and several observers representing various branches of American industry. Our Section Chairman, Mr. Franklin M. Depew, attended four Sessions of the Commission as an observer for the Food and Drug Law Institute. Detailed reports on the activities of the Codex Alimentarius Commission have been published in the Food Drug Cosmetic Law Journal[8] and else-

[8] Depew, "Report of the Fifth Session of the Joint FAO/WHO Codex Alimentarius Commission" 23 FOOD DRUG COSMETIC LAW JOURNAL 271 (May, 1968). Translations of various chapters, Second *(Continued on next page.)*

where,[9] and the official reports of the U. S. Delegates have been widely distributed. I assume therefore that most members of this Section are familiar with this subject matter and I shall limit myself to a few general comments.

By now the Codex Alimentarius Commission has worked out a very elaborate procedure for the drafting and consideration of standards by all parties concerned. It has delegated the actual task of drafting and processing the Standards to a number of Committees, six of which are World-Wide Subject Committees dealing with Food Additives, Food Hygiene, Food Labeling, General Principles, Methods of Analysis and Sampling, and Pesticide Residues. Then there are seven World-Wide Commodity Committees, an Expert Committee on Milk and Milk Products, an Expert Group on Fruit Juices and Quick Frozen Foods, and two Regional Codex Committees on Dietetic Foods and Natural Mineral Waters.

The procedure for the Commission for the elaboration of World-Wide Standards provides for ten steps. The first step is for the Commission to decide which of its Committees or subsidiary bodies is to be assigned this particular task. The second step is for the Committee to draft the Standard, the third step is for the Committee to send it to the governments of the member nations for comments, and so on, back and forth, until step 8 when the Commission votes the adoption of a draft as a "Provisional Standard." Then it is sent to the governments for formal acceptance, and as the tenth and last step it is

---

(Footnote 8 continued.)
Edition (1964) of the Latin-American Food Code have also been published in the FOOD DRUG COSMETIC LAW JOURNAL, as follows: Information concerning the Code and the Table of Contents of the New Edition appeared in the April 1965 issue of the FOOD DRUG COSMETIC LAW JOURNAL (Vol. 20, page 238). The first five chapters were published in the September 1965 issue; Chapters XII and XIII in the October 1965 issue; Chapter XVII in the November 1965 issue; Chapter X in the December 1965 issue; Chapter VII in the June 1966 issue; Chapter XVIII in the August 1966 issue; Chapter XVI in the May 1967 issue; Chapter VI in the August 1967 issue; Chapter XV in the October 1967 issue; Chapter XI in the August 1968 issue and Chapter IX in the November 1968 issue.

[9] "Forum on International Food Standards" published in 22 *Food Technology* 1118-1123 (September, 1968); Davies, "The Codex Alimentarius" 1118-1120; Grange, "United States Interest in Codex Alimentarius — A Government View" 1120; Stine, "United States Interest in Codex Alimentarius — An Industry View" 1120-1122; Peyton, "Activities of ISO, COPANT and USASI" 1122-1123; Jolly, "The Codex Alimentarius Commission in the United States—Organization, Procedure and Recommendations" 23 *Business Lawyer* No. 4 (July, 1968).

printed as the final World-Wide Codex Standard. The incorporation of a Standard into the Codex, however, does not make it automatically a part of the law of all the member nations. At this stage the member countries have several alternatives: (1.) Full acceptance of the Standard; (2.) Target acceptance—the country agrees to accept the Standard after a certain period of time; (3.) Acceptance with a declaration of more stringent requirements; (4.) Refusal to accept—with a full explanation of the reasons.

Another alternative of a "partial acceptance" was discussed but not accepted at the Fifth Session.

According to a recent article by J. H. V. Davies (U.K. Delegate)[10] eleven Standards have reached stage 9 and over 100 other Standards are being processed in the earlier stages. Consequently, the procedure is working successfully even though at a slow pace, and it is virtually certain that the first few Standards will reach the final stage before long.

To make any predictions about how many countries will accept the available final Standards without reservations would be a gambling game. One has to keep in mind, however, that not every government is free to give full acceptance to a Codex Standard without complying with the rules of procedure of its own national laws and this is particularly true of the U. S. Government. Nevertheless, one can anticipate a gradual "harmonization" of certain food standards on a world-wide basis as the result of the efforts of the Codex Alimentarius Commission.

Other organizations doing work on international standards which are closely related to food standards and, in fact, sometimes involve food standards as such, are the International Organization for Standardization (ISO) and the Pan American Standards Commission (COPANT) both of which cooperate closely with the USA Standards Institute (USASI). The ISO has one Technical Committee ISO/TC 34 for Agricultural Products which includes foods and feeds and which develops and recommends standards (mostly technical) for international use. COPANT, on the other hand, is a regional organization operating in Latin America and which has a close association with LAFTA.[11]

This is by no means a complete listing of international organizations engaged in the drafting of standards for foods and related items.

---

[10] See footnote 9.

[11] See footnote 9.

One of the most important tasks which needs to be performed during the next decade, in my opinion, is a better coordination of the efforts of all these organizations so as to avoid an unnecessary duplication of their efforts and to achieve a more effective implementation of their recommendations.

The task of a systematic international "approximation" or "harmonization" of food laws is being greatly aided by several educational and scientific institutions. The recently (1966) founded Food Law Research Centre at Brussels University under the direction of Professor E. J. Bigwood and Dr. A. Gérard undertook the publication of a four volume study entitled: "Fundamental Principles and Objectives of a Comparative Food Law", the first two volumes of which have already appeared.[12] The efforts of this Research Centre in Brussels and those of the older "German Association for Food Law and Food Science" in Bonn, and of the Food and Drug Law Institute in New York, contribute to the international discussion a wealth of factual information and scholarly thought and analysis which are so important in this very complicated field of knowledge. **[The End]**

SEIZURE UPHELD BY DISTRICT COURT

In granting a summary judgment on the ground that the product was an adulterated food, and contained a new drug introduced into interstate commerce without an approved New Drug Application, the U. S. District Court in Illinois upheld a government seizure of a shipment of a medicated animal feed. The Court ruled that the product was not "generally recognized as safe." The government's affidavits supported the position by demonstrating that the product, stipulated by the parties to be a food additive, as well as a drug, in animal feed, was not generally recognized by experts as having been shown through scientific procedures to be safe for its intended uses. The opposing affidavit of the claimant, the Court noted, could be construed only as a statement of opinion. There was no evidence to show that the claimant's expert was qualified by scientific training and experience to evaluate the safety and effectiveness of drugs for use in animals. In addition, the claimant's affidavit was based upon a theoretical evaluation of the active ingredients, and not addressed to the test of "general recognition."

The Court ruled that if no genuine difference of expert opinion as to the fact of general recognition is shown to exist, then summary judgment is proper.

U. S. v. 7 Cartons, * * *, (DC Ill., December 16, 1968), CCH Food Drug Cosmetic Law Reports ¶ 40,340.

---

[12] Volume 1 published in 1967, and Volume 2 published in 1968 by S. Karger, Basel, Switzerland. Distributors in the United States: Albert J. Phiebig, Inc., Box 352, White Plains, N. Y. 10602.

Authoritative Effect of FDA Regulations

By WILLIAM F. CODY

The Following Article Was Presented at the Joint Meeting of the Food and Drug Committee of the Administrative Law Section, and the Food, Drug and Cosmetic Law Division of the Corporation, Banking and Business Law Section, American Bar Association, Held in Philadelphia on August 7, 1968. Mr. Cody Is a Member of the Legal Department of the Corn Products Co., New York, N. Y.

THE COURTS, upon review or enforcement of federal agency regulations, accord varying degrees of authoritative effect to such regulations.[1] Regulations at one end of the spectrum of authoritative effect will, if enacted in accordance with statutory procedural requirements and not arbitrary or abusive of agency discretion, be treated by the court as tantamount to congressional legislation. At the other end of the spectrum, the court will determine the matter *de novo,* and in effect substitute the court's own judgment for the agency's regulation.

Administration, as the vehicle for the implementation of legislative or executive policy, continually requires choice of one interest over others. Since agencies are said to tend to consider the legitimacy of their actions secondary in importance to the positive solution of problems, we have good reason to look to the courts for the ultimate protection against executive abuse.[2] Insofar as it determines the extent of this ultimate protection, the matter of "authoritative effect" of regulations is critical to the fairness, and in the long view the efficacy, of our system of administration of laws. No one seriously suggests that the courts should supervise *every* action of *every* agency, or regularly substitute judicial discretion for agency discretion. How-

[1] By the term "regulations," I mean to restrict this discussion to agency "rules" as opposed to agency "orders" as those terms are defined in the Administrative Procedure Act. 5 U. S. C. 551(4).

[2] Jaffe, *Judicial Control of Administrative Action* (1965), 323-325.

ever, there are instances when judicial review is critical, regardless of the motives of the agency. As Justice Brandeis said in his dissent to the *Olmstead* decision:

"Experience should teach us to be most on our guard to protect liberty when the government's purposes are beneficent. . . . The greatest dangers to liberty lurk in insidious encroachment by men of zeal, well-meaning, but without understanding." *Olmstead v. U. S.*, 277 U. S. 438, 479-9, 72 L. Ed. 944 (1928).

The terms "legislative" and "interpretative" have been used to classify regulations with respect to authoritative effect, with the former considered to be subject to less judicial review than the latter.[3] Where the statute does not purport to create a substantive rule, but provides expressly that failure to comply with agency regulations on a particular subject will constitute a violation of the statute, the agency regulations are usually said to be "legislative." The term "interpretative" is usually applied where the statute *does* create a substantive rule, but where the statutory command is more or less general, and the agency (usually under general authority to make regulations for the enforcement of the statute) enacts a regulation interpreting and defining the general language of the statute.[4] Certainly, both the "legislative" and the "interpretative" rule may be "substantive," insofar as both may express standards of conduct.[5] The legislative-interpretative classification, and its implications for judicial review, were summarized by the Attorney General's Committee on Administrative Procedure in 1941:

"Administrative rule-making, in any event, includes the formulation of both legally binding regulations and interpretative regulations. The former receive statutory force upon going into effect. The latter do not receive statutory force and their validity is subject to challenge in any court proceeding in which their application may be in question. The statutes themselves and not the regulations remain in theory the sole criterion of what the law authorizes or compels and what it forbids. . . ."[6]

Legislative regulations are thus sometimes said to have the "force of law," insofar as they are subject to only the minimum judicial review, required by the Constitution and the Administrative Procedure Act.[7]

---

[3] For example, Davis, *Administrative Law* (1958), § 5.03.

[4] The terminology is not entirely satisfactory, as Professor Davis points out, since giving meaning to vague or ambiguous language may be as creative as any legislative process, though by the above criteria classified as interpretative. Davis, book cited at footnote 3, § 5.03, 304-305.

[5] "Opinion of Federal Trade Commission re Trade Regulation Rules (Advertising and Labeling of Cigarettes)" 29 Fed. Reg. 8324, 8365, note 131 (July 2, 1964).

[6] Report of Attorney General's Committee on Administrative Procedure (1941).

[7] 5 U. S. C. 704, 706.

Classification of a particular regulation as legislative or interpretative depends upon the legislative intent as manifested in the enabling statute. Subject to limitations regarding delegation of legislative powers, Congress certainly *may* delegate to an agency the power to "legislate" substantive standards not spelled out in the enabling statute.[8] However, Congress should not be deemed to have intended such a delegation of its legislative power where the delegation is not expressed in unequivocal terms. Where the delegation is explicit, the courts have found agency power to promulgate "legislative" regulations.[9] Otherwise, regulations should be presumed to be "interpretative."

Rules of Conduct

The Food and Drug Administration (FDA) has recently published proposed regulations with respect to "Current Good Manufacturing Practice" for human foods.[10] The proposed regulations, which I will hereafter refer to as the "food GMP regulations," establish rules of conduct for almost every aspect of the manufacturing, processing, packing and holding of food, from receipt of raw materials to the handling of finished product and from the design and condition of plant buildings and grounds to the processes, equipment and personnel training and hygiene.

Obviously, the authoritative effect of these regulations will be of considerable importance to the food industry. The proposed regulations themselves are not at all clear as to the authoritative effect they purport to have; they state only that the criteria specified in the regulations shall "apply" in determining whether foods are produced under "sanitary conditions." The notices of publication state that the regulations are promulgated under Sections 402(a)(4) and 701(a) of the Food, Drug & Cosmetic Act.[11] The sole substantive

---

[8] Davis, book cited at footnote 3, 302, (note 15).

[9] For example, *Boynton v. Pedrick*, 136 F. Supp. 888, 890 (SD NY 1954), aff'd 228 F. 2d 745 (CA-2, 1955). The statute provided that ". . . [W]henever in the opinion of the Commissioner the use of inventories is necessary . . . inventories shall be taken . . . upon such basis as the Commissioner . . . may prescribe as conforming . . . to the best accounting practice . . . and as most clearly reflecting the income." The court held that ". . . the effect of [the regulation enacted thereunder] as a legislative rather than an interpretive regulation is quite clear."

[10] The initial proposal appeared at 32 Fed. Reg. 17980 and following (December 15, 1967); a revised proposal was published at 33 Fed. Reg. 19023 and following (December 20, 1968).

[11] 21 U. S. C. 342(a)(4) ("A food shall be deemed to be adulterated . . . if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have

(Continued on next page.)

statutory basis for the regulations is clearly Section 402(a)(4)'s prohibition of ". . . insanitary conditions . . . whereby [the food] may have become contaminated with filth . . . ."[12] I will refer hereafter to that provision of the Act as the "Insanitary Conditions Provision."

The agency has described the food GMP regulations as follows:

"The FDA believes all of these businessmen processing or handling foods can be *significantly helped and kept up-to-date on current* good manufacturing practices if the essential principles are written into a set of regulations that will implement, *interpret, and have much the effect of the law* . . ." "GMP's For the Food Industry," *FDA Papers*, March, 1968, page 25 (emphasis added).

In other informal pronouncements, agency officials have indicated that regulations promulgated under Section 701(a) as the food GMP regulations would be, may have the "status of law" characteristic of legislative regulations.[13] The food industry quite clearly believes

(*Footnote 11 continued.*)
been rendered injurious to health.") and 21 U. S. C. 371(a) ("The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary."). There is no mention of "Current Good Manufacturing Practice" with respect to foods in the Act.

[12] It should be noted that the statute does not prohibit *all* insanitary conditions, but only those ". . . whereby [the food] may have become contaminated with filth . . ." In *Berger v. United States*, 200 F. 2d 818, 821-822 (CA-8, 1952), it was held that the quoted language implied a requirement of a "reasonable possibility" of contamination, and thereby afforded sufficient definition and warning of the prohibited conduct to preclude the defense of vagueness. The food GMP regulations define "sanitary conditions." (21 CFR § 128.2). The proposal of December 15, 1967, did not tie the proscribed practices to the "reasonable possibility" of contamination required by *Berger*. Therefore, the regulations did not appear to comprise a complete definition of the statutory standard of conduct. Most of the substantive provisions in the December 20, 1968 proposal prohibit the practices in question only where they may contribute to contamination of the food. (For example, 21 CFR § 128.3, 128.4, 128.6 and 128.7.) However, some of the substantive provisions of the December 20, 1968 proposal are not tied to the possibility of contamination of the food. (For example, 21 CFR § 128.5(a), (b), (c)(1), (c)(2) and (e); § 128.8(b)(3), (b)(4), (b)(5), (b)(6), (c) and (d).) The indefinite purport of the regulations is compounded by the fact that the regulations in the December 20, 1968 proposal are couched in varying terms, such as "should," "shall" or "must," in connection with substantive requirements. This usage apparently follows from FDA's statement in the notice accompanying publication of the proposal that some of the requirements are "mandatory" and others are "directory." The distinction is not entirely clear; however, it is apparently a measure of response to the industry position that these regulations should be no more than "guidelines."

[13] Goodrich, "Rule-Making as Viewed by the Commissioner, the Congress, and the Court," 22 FOOD DRUG & COSMETIC LAW JOURNAL 613 (1967); Goodrich, "Status of Major Proposals and Regulations," 22 FOOD DRUG & COSMETIC LAW JOURNAL 642 (1967).

that the regulations are "interpretative,"[14] and the question of the authoritative effect of the food GMP regulations will have to be determined by the courts in the near future.

Consideration of this question should begin with a review of the rule-making provisions of the Food, Drug and Cosmetic Act. With respect to the adulteration and misbranding of foods and drugs, the Act contains two basic rule-making provisions. Sections 701(e), (f) and (g), which I shall refer to as the "Special Rule-Making Provision," refer to six specific statutory provisions, and provide that regulations implementing those provisions will be subject to specified requirements of notice and hearing, evidence of record in support of findings and orders, and specific time and forum for judicial review.[15] The Insanitary Conditions Provision of Section 402(a)(4) is *not* one of the six provisions referred to in the Special Rule-Making Provision. All other rule-making proceedings (except those regarding statutory provisions which contain their own rule-making procedures or incorporate the Special Rule-Making Provision) fall under Section 701(a) (see footnote 11), which authorizes FDA to make regulations for the "enforcement" of the Act, and which I shall refer to as the "General Rule-Making Provision." It is therefore apparent, from the structure of the Act, that Congress contemplated two general categories of regulations, and that the food GMP regulations fall under Section 701(a), the General Rule-Making category. Neither the Special nor the General Rule-Making provision of the Act contains any express provision regarding the authoritative effect of regulations enacted thereunder.[16] However, the legislative history and the structure of the Act strongly suggest a distinction in this respect between these two categories of regulations.

Legislative Regulations

In the House Committee Report accompanying the bill which became the 1938 Food, Drug and Cosmetic Act, the statutory provi-

[14] See Comments filed with the Department of Health, Education and Welfare Hearing Clerk with respect to the proposed regulations (footnote 10).

[15] 21 U. S. C. 371(e), (f) and (g).

[16] The Special Rule-Making Provision, however, implies, by its "substantial evidence of record" criterion for agency action, that a reviewing court may not substitute its own discretion for that of the agency, whereas the General Rule-Making Provision contains no such implication. See *Federal Security Administrator v. Quaker Oats Co.*, 318 U. S. 218, 63 S. Ct. 589 (1943) and *Willapoint Oysters, Inc. v. Ewing*, 174 F. 2d 676, 686 (CA-9, 1949). See also *Byrd v. United States*, 154 F. 2d 62, 63 (CA-5, 1946), which holds that the rule-making authority under Sections 701(e) and 604 (relating to coal tar colors and since repealed) was "quasi-legislative" in nature.

sions referred to in Section 701(e), the Special Rule-Making provision, were said to authorize regulations which would have the "force of law" rather than being "merely interpretive," and violations of which would constitute violations of the statute.[17] Congress thus clearly intended regulations enacted under the Special Rule-Making Provision to be "legislative." On the other hand, no specific statement was made as to the authoritative effect of regulations enacted under Section 701(a), the General Rule-Making Provision, which (together with the Insanitary Conditions Provision) was also enacted into law in the 1938 Act. Congress therefore appears to have delegated "legislative" rule-making authority only pursuant to the Special Rule-Making Provision, and in the General Rule-Making Provision, to have conferred the power to enact only what the Congress referred to as "merely interpretive" regulations.[18]

This dichotomy is further illustrated by the structure of the statute itself. The statutory provisions referred to in Section 701(e), the Special Rule-Making Provision, insofar as they provide for regulations, do not themselves contain any complete substantive rules of conduct unless and until the FDA regulations thereunder have been enacted. These provisions are not self-executing; Congress has intentionally left interstices in the statutory scheme, which are intended to be filled by agency regulations. For example, Section 403(j) provides that a food for special dietary use shall be deemed misbranded unless its label shall contain the information required by FDA regulations.[19] There can be no violation of this provision until there are regulations; the regulations authorized by this provision are thus clearly "legislative" in nature. On the other hand, the basic statutory provisions *other* than those referred to in the Special Rule-Making Provision, *are* clearly self-executing. For example, it has been held that

[17] "Such regulations [that is, 701(e) regulations] are *not merely interpretive. They have the force and effect of law and must be observed.*" H. Report No. 2139, 75th Cong., 3d Sess. (1938), page 12 (emphasis added).

[18] See footnote 17. A further statement in H. Report No. 2139 (Page 11) reinforces this interpretation: "Section 701 relates generally to regulations. In the case of *regulations, the violation of which constitutes an offense,* it is required that appropriate notice of a public hearing be given and that adequate time shall be given after the promulgation of a regulation before it becomes effective." (emphasis added). Since only the Special Rule-Making Provision requires notice, hearing and postponed effective date, there is a strong suggestion in the quoted language that only the regulations enacted under the Special Rule-Making Provision were intended to have legislative effect.

[19] "A [special dietary] food shall be deemed to be misbranded . . . unless its label bears such information . . . as the Secretary . . . by regulations prescribes . . . ." 21 U. S. C. 343(j).

Section 402(a)(4), the Insanitary Conditions Provision, affords in itself a substantive rule of conduct.[20] The Supreme Court has ruled that the more nearly self-executing a statute, the lesser the delegation of rule-making power to the agency that is to be implied.

"The wider a delegation is made by Congress to an administrative agency the more incomplete is a statute and the ampler the scope for filling in, as it is called, its details."[21]

It thus seems reasonable to infer from the structure of the statute itself that Congress intended to delegate no more than interpretative rule-making authority with respect to the Insanitary Conditions Provision.

The "Force of Law" Concept

Several recent judicial pronouncements, however, may appear to suggest that regulations promulgated under the General Rule-Making authority of Section 701(a) have the "force of law." However, it is my opinion that these decisions relate only to "force of law" with respect to "ripeness" for judicial review, and do not deal at all with the question of the authoritative effect of the regulations with respect to scope of judicial review. In *Abbott Laboratories v. Gardner*, CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,258, 387 U. S. 136, for example, the Supreme Court made the following statement with respect to regulations promulgated under Section 701(a):

"These regulations are not meant to advise the Attorney General, but *purport* to be directly authorized by the statute. Thus, *if within the Commissioner's authority*, they have the *status of law* and violations of them carry heavy criminal and civil sanctions . . ." Pages 151-52 (emphasis added).

This statement, however, was made in the context of the question decided—ripeness (that is, timeliness) for *any* judicial review whatsoever, rather than the appropriate scope (that is, quantum) of judicial review when judicial review is in fact granted. Among other requisites, regulations are ripe for judicial review only if they have an immediate effect upon the conduct of the regulated persons.[22] Regulations purporting to comprise self-executing rules of conduct are said to have such immediate effect, and this effect is often referred to by the courts as the "force of law." In its treatment of this concept of immediate effect, the *Abbott* decision relied heavily upon *CBS, Storer*

[20] See *Berger v. U. S.*, see footnote 12; *U. S. v. 1500 Cases . . . Tomato Paste*, 236 F. 2d 208, 212 (CA-7, 1956); and cases cited in the latter decision.

[21] *Addison v. Holly Hills Fruit Products*, 322 U. S. 607, 616, 88 L. Ed. 1488 (1944).

[22] *Columbia Broadcasting System v. U. S.*, 316 U. S. 407, 86 L. Ed. 1563 (1942); *U. S. v. Storer Broadcasting Co.*, 351 U. S. 192, 100 L. Ed. 1081 (1956); *Frozen Food Express v. U. S.*, 351 U. S. 40, 100 L. Ed. 910 (1956).

and *Frozen Food Express,* (see footnote 22). The latter three decisions found regulations ripe for review upon the grounds that the regulations had, as the proposition was stated in *Frozen Food Express,* ". . . immediate and practical impact . . .", and that regulated persons, who disregarded the regulations, did so, ". . . at the risk of incurring criminal penalties . . ." and that the regulations were ". . . not therefore abstract, theoretical, or academic . . ." and were therefore ripe for judicial review.[23] On the other hand, a regulation which provides only that certain action "may be" taken by an agency in the event of particular conduct by a regulated party lacks this immediate effect.[24] The term "status of law" is used in the *Abbott* decision only with respect to this concept of immediate effect as related to ripeness, and the statement quoted above from the *Abbott* decision thus relates only to ripeness. The appropriate *scope* of judicial review was not before the Court in *Abbott,* which involved an appeal from the District Court's dismissal of a complaint by reason of non-ripeness, nor was the question of scope of review involved in the companion cases, *Gardner v. Toilet Goods Association,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,260, 387 U. S. 167, 18 L. Ed. 2 704 (1967) and *Toilet Goods Association v. Gardner,* (see footnote 24), where the appeals had been taken before any trial had been had on the merits, and the only question presented was ripeness.

"Force of law" with respect to ripeness is therefore not related to authoritative effect or scope of review, and thus does not bear at all upon the "legislative-interpretative" classification question.[25] In *Storer,* on which the Supreme Court relied substantially in the *Abbott* decision, the court found FCC's maximum-station-ownership regulation to have the force of law with respect to ripeness. However, in

[23] See footnote *22,* 351 U. S. at 44.

[24] *Toilet Goods Association v. Gardner,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,259, 387 U. S. 158, 164 (1967).

[25] The argument was advanced by FDA in the *Abbott* and *TGA* cases that since the regulations involved were "interpretative" rather than "legislative," they were not ripe for review. See, for example, Brief for Respondents Gardner et al (pp 8-11, 15) in *Abbott Laboratories v. Gardner,* above. Of the courts involved in the *Abbott* and *TGA* litigation, only the Third Circuit Court of Appeals found this "legislative-interpretative" distinction relevant to the ripeness issue, (See *Abbott Laboratories v. Gardner,* CCH FOOD DRUG COSMETIC LAW REPORTS ¶ 40,206, 352 F. 2d 286, 289 (CA-3, 1965)), and the Third Circuit's ripeness ruling was reversed by the Supreme Court. Indeed, the District Court and the Court of Appeals in *TGA* stated unequivocally that the "legislative-interpretative" distinction was not even germane to the issue of ripeness. *Toilet Goods Association v. Celebrezze,* 235 F. Supp. 648,65, (SD NY, 1964); *Toilet Goods Association v. Celebrezze,* 360 F. 2d 677, 686 (2d Cir., 1966), and these rulings were affirmed by the Supreme Court.

response to Storer's argument that such prospective rule-making deprived Storer of its right to a hearing on specific facts, the Court stated emphatically that the regulation would be subject to further review when applied to specific adjudicative situations, in spite of the fact that the maximum number of stations specified in the regulations purported to be a final rule. The Court said:

> We read the Act and Regulations as providing a "full hearing" for applicants who have reached the existing limit of stations, upon their presentation of applications . . . that set out adequate reasons why the Rules should be waived or amended. (See footnote 351 U. S. at 205.)[26]

Thus, although the rules had such "force of law" as to be ripe for review, affected parties retained the right to question the reasonableness of the rules as applied to specific fact situations; clearly the rules did not have such "force of law" as to be considered "legislative rules" for purposes of scope of review and authoritative effect.

"Force of law" for ripeness purposes, therefore means the immediacy of injury from what the agency has *purported* to do or require in its regulation, and it stops short of the question of whether the agency has the power, or correctly exercised the power, to do or require what its regulation purports.[27] It is somewhat akin to a motion addressed to the sufficiency of a pleading; for purposes of the motion, the pleading is taken at face value, and its allegations are presumed to be true. However, if the motion is denied, the allegations must thereafter be proven at trial. In *Abbott*, the Supreme Court decided that the regulations were "ripe" for review, but left open the question of whether the regulations were "within the Commissioner's authority."[28] Furthermore, in the case of the regulations found ripe for review (and thus having the "force of law" for ripeness purposes) in *Gardner v. TGA*, the District Court, on remand, reviewed the regulations to that broad extent which Professor Davis calls "substitution of the court's judgment for the agency's."[29] The Supreme Court's determination that these regulations had the "force of law" for ripeness purposes did not deter the District Court from holding that the regulations exceeded FDA's statutory authority. Although the District

[26] See also *NBC v. U. S.*, 319 U. S. 190, 225, 87 L. Ed. 1344, 1367 (1943), where a similar statement was made with respect to the Chain Broadcasting Regulations involved in *CBS v. U. S.*, see footnote 22, another decision upon which the *Abbott* decision relied.

[27] See, for example, *CBS v. U. S.*, 316 U. S. at 422 (regulations were ". . . *couched* in terms of command . . . and . . . must be taken by those entitled to rely upon them as what they *purport to be.*") (emphasis added); *Abbott Laboratories v. Gardner*, 387 U. S. at 151-152.

[28] See footnote 27, 387 U. S. at 151.

[29] *Toilet Goods Association v. Gardner*, 278 F. Supp. 786 (SD NY, 1968); Davis, book cited at footnote 3, § 5.03 p. 315.

Court did not discuss the appropriate scope of review, its statement that the regulations were to be deemed valid in the absence of a showing that ". . . they are plainly inconsistent with the statute they seek to interpret . . .", indicates that the Court considered the regulations to be "interpretative" regulations for purposes of scope of review. (Page 789.) I therefore believe that *Abbott* and *TGA,* and their predecessor decisions, interpret the "force of law" concept only for ripeness purposes, and have no decisional effect regarding the scope of judicial review to be accorded FDA regulations enacted under Section 701(a).[30]

Implied Delegation of Authority

Another decision which is said to suggest that FDA has legislative rule-making authority under the General Rule-Making Provision is *U. S. v. 1500 Cases . . . Tomato Paste.*[31] The first violation of the Act charged in that case involved Section 402(a)(3) of the Act.[32] The Court ruled that that provision had to be interpreted to authorize FDA to promulgate tolerances for filth, in order to avoid a rule which would prohibit even the minute, inconsequential quantities of filth which are apt to be present in virtually all foods. With respect to Section 402(a)(3), the Court said:

> The Food and Drug Administration should set definite standards in each industry which, if reasonable, and in line with expressed Congressional intent, would have the force of law. . . . We believe that if the fact that almost all food contains some filthy, putrid, and decomposed substances had been called to the attention of Congress, that body would have directed the administrator to provide reasonable and acceptable tolerances for these substances just as it did in the case of poisons. (See page 211.)

In effect, Section 402(a)(3) did not, in itself, express a complete, viable substantive rule of conduct. From the latter fact, and from the fact that Congress (when it *was* aware of the fact that not all poisons could be removed from foods) did provide legislative rule-

[30] A detailed discussion of whether the food GMP regulations will, upon final promulgation, be ripe for review is outside the scope of this paper. Briefly, however, I believe that they will probably not be found ripe for review. Although they might be said to have the "force of law" for ripeness purposes, this factor alone is not dispositive of ripeness. The *Abbott* decision specifies other tests which must be met for regulations to be ripe for review—e. g., gravity of consequences of deferred review and presentation of a clear legal question which can be decided by a court absent a concrete enforcement context—and the food GMP regulations (or at least most of them) probably do not meet all of the *Abbott* criteria.

[31] See footnote 20.

[32] 21 U. S. C. 342(a)(3), which provides that a food shall be deemed adulterated ". . . if it consists in whole or in part of any filthy, putrid, or decomposed su[b]stance, or if it is otherwise unfit for food."

making authority for tolerances in other provisions of the Act, the Court found an implied delegation of legislative rule-making authority. With respect to the second charge, under the Insanitary Conditions Provision, the Court expressed the following dictum:

> [W]e have a natural tendency to equate the standard with the average condition of canneries throughout the country. If the Federal Food and Drug Administration desires to improve that average, it would be more likely to receive the support of the courts if it promulgated regulations which provided detailed standards as to cleaning procedures, screens, hygiene facilities, etc., publishing them to food packers as the requisites for complying with 21 U. S. C. A. § 342(a)(4), and *then* seizing food packed in plants not meeting the specific standards set.... Page 212.

This dictum does not necessarily mean that regulations regarding the Insanitary Conditions Provision will be given legislative effect. No implied Congressional delegation was even mentioned by the Court with respect to the Insanitary Conditions Provision, and such delegation is critical to the existence of legislative rule-making authority. Moreover, the Insanitary Conditions Provision *has* been held to express a complete, viable substantive rule of conduct.[33] The Court simply says that if FDA desires to improve the industry average (the standard implied), FDA should promulgate standards, before seizing products manufactured in circumstances no worse than the industry average. Nothing is said of any authoritative or binding effect of such standards upon courts. To advise and guide the industry before enforcement action would be sensible, fair regulatory practice and would not presuppose binding, legislative regulations. The dictum thus contains no implication as to the legislative or interpretative character of regulations relating to Insanitary Conditions.

I might also point out that FDA has stated informally that before proposing these food GMP regulations, it solicited industry views, "[A]lthough not required to do so by statute. . . ."[34] This is apparently a reference to the exception from Section 4 of the Administrative Procedure Act's requirement of notice of proposed rule-making in the case of ". . . interpretative rules . . .,"[35] and indicates that FDA itself has treated these regulations as "interpretative."[36]

I therefore conclude that the food GMP regulations are properly classified as interpretative for purposes of scope of judicial review.

---

[33] See *Berger v. U. S.*, footnote 12.

[34] See "GMP's For the Food Industry" *FDA Papers*, March, 1968, page 25.

[35] 5 U. S. C. 553(b).

[36] See *American President Lines Ltd. v. Federal Maritime Commission*, 316 F. 2d 419, 422 (DC Cir., 1963), holding that regulations published without notice, pursuant to this exemption from APA notice requirements, are merely opinions of the agency and do not bind the court unless it elects to adopt them.

The Spectrum of Authoritative Effect

The second aspect of the question is the appropriate scope of review of the FDA food GMP regulations as "interpretative" regulations. Interpretative regulations may be given varying degrees of authoritative effect by reviewing courts, ranging from virtually binding effect, at the one extreme, through a highly persuasive effect, in the middle of the spectrum, to merely advisory or guidance effect which the court may overlook if it wishes, at the other end of the spectrum.[37] The factors which the court will consider, in classifying a regulation somewhere on this spectrum of authoritative effect, are:

(1) Whether the court agrees with the regulation;

(2) Whether administrative expertise, and judicial inexpertise, characterize the subject matter;

(3) Whether the regulation is a construction made contemporaneously with the enactment of the statute by persons likely to have participated in its enactment;

(4) Whether the regulation has been long in effect; and

(5) Whether the statute has been re-enacted with the regulation in effect and known to the legislature.[38]

With respect to the food GMP regulations, the first and second factors noted above would be the only relevant factors, the first being likely to serve frequently as an "unarticulated major premise." The second factor, agency expertise and judicial inexpertise, has been described by the Supreme Court, in the context of the National Labor Relations Board's rule-making powers, as follows:

> We consider that the rulings . . . of the administrator under this Act, while not controlling upon the courts by reason of their authority, do constitute a body of experience and informed judgment to which courts and litigants may properly resort for guidance. The weight of such a judgment in a particular case will depend upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control. *Skidmore v. Swift & Company,* 323 U. S. 134, 136-140, 89 L. Ed. 124, 129(1944).

Certainly, the technical expertise and accumulated experience of FDA require that some persuasive effect should be given to the food GMP regulations by a court in an enforcement action. The food manufacturing industry, with its implications for the public health, is simply too complex, and too sensitive, an area for a court to set itself up as an expert with qualifications equal to those of FDA in

[37] Davis, book cited at footnote 3, § 5.05, p. 314, and following, and cases cited therein.

[38] See footnote 37, § 5.03 p. 300.

the area of contamination or adulteration of foods. I would expect the courts to treat these regulations in the manner in which the Supreme Court, in the language quoted earlier from the *Skidmore* decision, has treated agency rulings embodying agency expertise and experience. Such treatment should, in any event, provide for a full hearing by the court as to the reasonableness of the regulations as applied to the particular factual context. This would not be *de novo* review, but rather consideration of whether the interpretation set forth in the regulation should be applied in a specific factual context. It would, in effect, consist of a finding by the court as to whether the practice in question would, in the particular context, result in a reasonable possibility of contamination of the food product.

Federal Trade Commission (FTC)

The Federal Trade Commission (FTC) has taken such a position with respect to enforcement proceedings involving regulations of general and prospective effect, in the context of an enabling statute which more clearly justifies substantive rule-making of this nature than does the Food, Drug and Cosmetic Act.[39] In its opinion regarding the cigarette advertising Trade Regulation Rule, the FTC provided an excellent analysis of the authoritative effects of its Trade Regulation Rules. The FTC first pointed out that it has statutory power to adjudicate with respect to advertising practices, and thus to create substantive law on a case-by-case basis, and also that it has been empowered by Congress to create preventive, rather than punitive, trade regulation policy.[40] These considerations, together with the exhortations of courts and commentators that agencies do more by way of prospective rule-making and less adversary adjudication, suggested to the FTC that it should proceed, in certain areas, by prospective rule-making.[41] The opinion lists ten specific factors which favor prospective rule-making over case-by-case adjudication as a means for developing substantive law.[42] As far as statutory authority to promulgate the trade regulation rules, the Commission

[39] See "Opinion of Federal Trade Commission re Trade Regulation Rules (Advertising and Labeling of Cigarettes)," footnote 5.

[40] See footnote 39, at pages 8364-8374.

[41] See footnote 39, 8365—8369.

[42] See footnote 39, 8366-8368. Some of those factors are: industry-wide application (rather than singling out adjudicative respondents, particularly with respect to novel policies); participation of all interested parties rather than one or a few respondents; more likelihood of getting useful legislative facts and opinions into the record; prospective guidance to avoid uncertainty; and avoidance of costly adjudicative determinations.

held that the general rule-making power set forth in Section 6(g) of the Federal Trade Commission Act,[43] plus the congressional purpose of the Act to *prevent* unfair trade practices, empower the FTC to define and particularize by regulations the substantive requirements of the Act. As far as the effect of trade regulation rules in adjudicative proceedings, the Commission stated that such rules fit neither of the conventional pigeonholes—"legislative" or "interpretive"—exactly.[44] The Commission stated that in future individual adjudicative proceedings, it *may* rely upon the findings of fact, to the extent that they are "legislative facts" (that is, background facts of broad, general application) and upon considerations of law, policy, discretion and accumulated experience embodied in the trade regulation rule-making findings and conclusions, *provided* that no respondent's right to a full trial-type hearing will be infringed.[45] The Commission stated that the individual respondent is entitled to challenge the propriety of applying the rule to him in an adjudicatory proceeding, by reason of the *Storer* and *NBC* decisions, (see footnote 22), *FPC v. Texaco Inc.*, 377 U. S. 33, 12 L. Ed. 2 112 (1964), and the "official notice" provision of the Administrative Procedure Act.[46] Persons who wish to demonstrate that the rule should be amended or waived in the specific circumstances of later enforcement proceedings will be allowed to present evidence and argument as to such "adjudicative fact" issues, as opposed to the "legislative fact" issues. This would not be a *de novo* hearing, but rather a hearing on the appropriateness of applying general policy ("legislative facts") to a respondent's particular conduct ("adjudicative facts").[47]

In summary, the FTC, in spite of its recitation of statutory authority and policy reasons for substantive law-making, decided that its prospective rule-making powers are less than unqualifiedly "legislative." Although an agency is hardly the proper party to define its own delegated powers,[48] this rather restrictive agency view of the authoritative effect of its own regulations is most persuasive.

---

[43] 15 U. S. C. 46(g), which authorizes the Commission ". . . to make rules and regulations for the purpose of carrying out the provisions of [the Act]."

[44] See footnote 39, 8371.

[45] See footnote 39, 8371-8372.

[46] 5 U. S. C. § 556(e).

[47] This suggests that the trade regulation rules do little more than to establish a prima facie case, and to shift to the respondent the burden of coming forward with rebuttal.

[48] *Addison v. Holly Hill Fruit Products*, see footnote 21 at 616; *U. S. v. . . . Bacto-Unidisk*, CCH Food Drug Cosmetic Law Reports ¶ 80,194, 392 F. 2d 21 (CA-6, 1968); review granted, 37 U. S. L. Week 3147 (October 22, 1968).

The logic of the FTC cigarette advertising opinion regarding the right to a fair hearing on the "adjudicative facts" in an enforcement proceeding, is applicable to the FDA food GMP's. FDA has no adjudicative function regarding the Insanitary Conditions Provision and thus (unlike FTC) FDA has no expressly delegated power to create substantive law in this area. On the face of the statute, and in practice, FDA is an enforcement agency with respect to this provision. The power to enact these food GMP regulations, and therefore their authoritative effect, appears to be somewhat less than the FTC's power to enact trade regulation rules. I would conclude that the FDA food GMP's should be treated by a court as expert determinations of general policy which may be judicially noticed by the court as "legislative facts," but which should not preclude the court from its own determination upon particular "adjudicative facts."[49]

This flexibility of application is particularly essential in the case of the food GMP regulations, since those regulations define "insanitary conditions," whereas the Act prohibits only those ". . . insanitary conditions *whereby* [the food product] *may have become contaminated with filth* [*etc.*]." (emphasis added).[50] The requirement of a reasonable possibility of contamination, etc., has been held essential to the constitutionality of the Insanitary Conditions Provision of the Food Drug and Cosmetic Act in *Berger v. U. S.*[51] It appears to be the kind of "adjudicative fact" issue the FTC referred to in the Cigarette Trade Regulation Rule opinion. Each claimant or defendant in an enforcement action should therefore have full opportunity to litigate this "reasonable possibility" in the light of the specific practice or condition involved in his case, as a basic "adjudicative fact" issue as to which he is entitled to an individual hearing by the Court. Fundamental considerations of fairness, and constitutional due process, would seem to require no less. **[The End]**

---

[49] The District Court for the Eastern District of New York appears to tend toward this type of treatment of the pharmaceutical GMP regulations in *U. S. v. Bel Mar Laboratories Inc.*, 284 F. Supp. 875 (DC NY, 1968). In a preliminary decision on the adequacy of the information, which apparently stated the charge in the statutory language, the court referred to the pharmaceutical GMP regulations as "interpretive regulations" which are "available [to the industry] for guidance" as to the meaning of the broad statutory language.

[50] 21 U. S. C. 342(a)(4).

[51] *Berger v. U. S.*, see footnote 12, at 821-822.

Intensified Inspections— A Rule of Reasonableness

By VINCENT A. KLEINFELD

The Following Article Was Presented at the Semi-Annual Meeting of the National Association of Pharmaceutical Manufacturers, in Washington, D. C. on January 29, 1969. Mr. Kleinfeld Is a Member of the District of Columbia Bar.

ALL OF US MUST BE AWARE by this time of the intensified inspections of drug establishments which have been, are being, or will be conducted in the future by the Food and Drug Administration (FDA). These inspections have taken weeks and in some instances months. FDA inspectors come into a plant and become one of the family—they stay there and give periodic accounts of the conditions they find which, in their opinion, are improper or inappropriate.

This is a distinct innovation and the next step, of course, may be the stationing of resident inspectors in drug plants. After all, it can be argued with some reason that if resident inspectors are needed in meat or poultry establishments, why not in drug plants? In fact, why not in any food factory? The costs of these expansions will, of course, be tremendous, but we have long passed the point where Congress is interested in these costs and the concomitant higher prices to the consumer.

In any event, let us be a little bit conservative, if not reactionary, and examine the legal authority for these intensified inspections. The factory inspection section of the Federal Food, Drug and Cosmetic Act must be relied on by the government for its right to inspect and the scope and extent of inspection. Both the original factory inspection section, which was a very salutary part of the Act when it was passed in 1938, and the revision of the section enacted by Congress in 1953, after the original section had been declared unconstitutional by the Supreme Court because of ambiguity, were very precise in provid-

ing for "reasonable" inspections. The section provides for the entry of inspectors "at reasonable times," inspection "at reasonable times," and that the inspection must be "within reasonable limits" and performed "in a reasonable manner." Each inspection must be commenced and completed "with reasonable promptness." Can it be reasonably said that an inspection which extends for weeks and months is being conducted "at reasonable times," "within reasonable limits," "in a reasonable manner," and is being completed "with reasonable promptness"?

The Criterion of Reasonableness

In my view, courts would not hold that an inspection extending for weeks and months is authorized by the factory inspection section of the statute. The legislative history, as well as the explicit language, of the factory inspection section, reveals that Congress was very deliberate in creating the criterion of reasonableness in inspections. For example, Congressman Wolverton, the sponsor of the amended section, stated that the purpose of the adoption of some of industry's objections "was to protect the rights of those whose premises are inspected and make certain that the inspections should be conducted in a reasonable manner . . . ." The following colloquy in the House of Representatives is also pertinent:

MR. COLE: The inspector could, if he wanted to, harass a certain manufacturer; he could continually inspect and inspect. There is no limitation on that under the bill.

MR. PRIEST: There are limitations in what he may do, and I think those requirements rather considerably limit the inspector, in addition to the fact that it must be at a reasonable time and in a reasonable manner.

And Congressman Beamer stated:

> All of these witnesses were in favor of factory inspection, but all who were connected with any type of manufacture or distribution of food, drugs and cosmetics were hopeful that some provisions of limitations would be included in order to protect the manufacturer from certain practices of inspectors and other officials. It was for this reason that the word "reasonable" was applied to time, manner, and limit of inspection . . . .

Further, in H. R. Report No. 708, 83rd Congress, 1st Session, the House of Representatives Committee on Interstate and Foreign Commerce pointed out that the amended factory inspection section was "intended to provide compulsory, but limited, inspection authority . . . the committee is of the opinion that . . . it is imperative to

limit the power and scope of inspection to be granted to the Food and Drug Administration."

There is one further important limitation on the inspection authority granted to the government by the Federal Food, Drug and Cosmetic Act of 1938. In 1967, the Supreme Court of the United States rendered two important decisions which bear directly and decisively on the right and scope of factory inspection by the FDA.

In one case, a homeowner, awaiting trial on a criminal charge of violating a city housing code by refusing to permit a warrantless inspection of his residence, sought a writ prohibiting the criminal court from proceeding on the ground that the ordinance authorizing the inspection was unconstitutional. A city inspector had entered an apartment building to make a routine annual inspection for possible violations of the city's housing code. The manager informed the inspector that the plaintiff, lessee of the ground floor, was using the rear of the building as a personal residence. Claiming that the building's occupancy permit did not allow residential use of the ground floor, the inspector demanded that the plaintiff permit an inspection of the premises. The plaintiff, one of those unusual, rugged individualists, now so few in number, refused to allow the inspection because the inspector lacked a search warrant. He was then prosecuted for having refused to permit inspection. The Supreme Court held for the plaintiff, declaring that the city housing code, which authorized municipal officials to enter a private dwelling without a search warrant and without probable cause, violated the Fourth Amendment to the Constitution of the United States, which provides that: "The right of the people to be secure in their persons, houses, papers, and effects, against unreasonable searches and seizures, shall not be violated, and no Warrants shall issue but upon probable cause, supported by Oath or affirmation, and particularly describing the place to be searched, and the persons or things to be seized."

The Supreme Court pointed out, as it has in many cases, that the basic purpose of the Amendment is to safeguard the privacy and security of individuals against arbitrary invasions by government officials, and that the Amendment "thus gives concrete expression to a right of the people which 'is basic to a free society'." The Court refused to hold that fire, health, and housing inspection programs are outside of the scope of the Amendment.

The Supreme Court adverted to the contention that the health and safety of entire populations is dependent upon enforcement of

various codes and that the only effective means of enforcing them is by routine inspection of all physical structures. But the Court refused to accept this argument, stating that the question was not whether the inspections might be made but whether they might be made without a search warrant, and that it had not been established that the inspection programs involved could not achieve their goals within the confines of a reasonable search warrant requirement. The Court concluded by declaring that such inspections (and there is no doubt but that this would include inspections under the Federal Food, Drug and Cosmetic Act) are significant intrusions upon the interests protected by the Fourth Amendment and that such searches, when authorized and conducted without a warrant, lack the traditional safeguards which the Amendment guarantees to the individual.

The Supreme Court did hold, however, that it was not essential that search warrants should issue only when the inspector possessed probable cause to believe that a particular dwelling contained violations and that an entire area inspection might be authorized. The Court stated that in determining whether there is probable cause to issue a search warrant, the need for the inspection must be weighed in terms of the reasonable enforcement goals, and that probable cause to issue a warrant exists in the event reasonable legislative or administrative standards for conducting an area inspection are satisfied with respect to a particular dwelling. The Court pointed out that such standards, which will vary with the particular governmental program being enforced, may be based upon the passage of time, the nature of the building, or the condition of the entire area, but they will not necessarily depend upon specific knowledge of the condition of the particular dwelling.

The Supreme Court stressed reasonableness, and held that the warrant procedure was designed to guarantee that a decision to search private property is justified by a reasonable governmental interest and that if a valid public interest justified a proposed inspection then there was probable cause to issue a "suitably restricted search warrant." The use of the last four words is particularly pertinent.

In a companion decision, decided by the Supreme Court on the same day, a defendant sought reversal of his conviction for having refused to permit a representative of the City of Seattle Fire Department to enter and inspect his locked commercial warehouse without a warrant and without probable cause to believe that a violation of any municipal ordinance existed. The Court reversed the conviction,

holding that administrative entry, without consent, upon portions of commercial premises which are not open to the public may only be constitutionally compelled within the framework of a search warrant procedure. The Court stated, in part:

> . . . a search of private houses is presumptively unreasonable if conducted without a warrant. The businessman, like the occupant of a residence, has a constitutional right to go about his business free from unreasonable official entries upon his private commercial property. The businessman, too, has that right placed in jeopardy if the decision to enter and inspect for violation of regulatory laws can be made and enforced by the inspector in the field without official authority evidenced by a warrant.

It is interesting to note, also, that a United States Court of Appeals held recently that drug repackers who had permitted an inspection of their factory did not waive their protection under the Fourth Amendment to refuse an FDA inspector access to their records of receipt and distribution of prescription drugs, and that the protection of the Amendment against unlawful search and seizure applies to drug records as well as drug factories. The Court stated that, since the notice of inspection presented by the inspector did not authorize an inspection of the records, the repackers, by permitting a factory inspection, did not waive their right under the Fourth Amendment to refuse an inspection of their records. The Court pointed out that, even though the factory inspection section of the Federal Food, Drug and Cosmetic Act permits an inspection of certain records dealing with prescription drugs, the Supreme Court rulings I have referred to establish the principle that the confines of a search must be delimited by designating the needed documents in a search warrant if the demand for the documents has been refused. The Court concluded that, since the refusal was protected by the Fourth Amendment and the repackers had not waived that protection, the criminal convictions of the drug repackers for their refusal to permit inspection of their prescription drug records had to be reversed.

It is clear, therefore, that as a matter of constitutional law an FDA inspector may be denied the right to enter and inspect a drug establishment unless and until he obtains a search warrant. This is not to say, by any means, that the inspector should be denied entry when he seeks to inspect under the factory inspection section of the Act. No one, in my opinion, can reasonably disagree with the necessity of reasonable factory inspections if the FDA is to administer and enforce the Federal Food, Drug and Cosmetic Act effectively and perform its duty to protect the consumer. One of the more important accomplishments of the 1938 Act was the provision for factory inspec-

tion. But whether an inspection of weeks and months is reasonable or necessary for effective enforcement of the statute would indeed appear to be debatable. Certainly, the FDA has appeared to have gotten along quite well since 1938 in the unintensified inspections which have been made up to the present.

In my opinion, the Supreme Court, in abolishing (in the decisions I have mentioned) the distinction between criminal searches and searches such as those involved in the factory inspection section, was correct, since the protection of privacy was the essential reason for the provision of the Fourth Amendment with respect to search warrants. I feel that we cannot differ with the Supreme Court's statement that "it is surely anomalous to say that the individual and his private property are fully protected by the Fourth Amendment only when the individual is suspected of criminal behavior." I cannot quarrel, however, as some have done, with the Supreme Court's proposal of a new standard for administrative inspections while retaining the traditional standard for criminal searches. Apparently, under the standard for administrative inspections such as those under the factory inspection section of the 1938 Act, the inspector would not be required to have probable cause to believe in all instances that a specific violation of the statute actually exists.

The Basis for Issuing Search Warrants

What can we conclude, therefore, with regard to these intensified inspections? As I review the situation, it is clear that the basic criterion is reasonableness. More important than my opinion, of course, is the constitutional requirement in the Fourth Amendment that search warrants are required and that they be issued only upon probable cause under the circumstances and in the administrative situation involved. I find it most difficult indeed to believe that, in the ordinary typical situation, the courts would grant a search warrant providing for an inspection of many weeks or months and unlimited in scope, extent, and character.

Similarly, when inspection is demanded and granted on the basis of a notice of inspection under the factory section of the Federal Food, Drug and Cosmetic Act, the inspection must be conducted in a reasonable manner and concluded within a reasonable period of time. If not, in my view, further inspection may be refused.

One further point is worthy of consideration. Everyone, including the Supreme Court, talks blithely of obtaining a search warrant.

The Federal Rules of Criminal Procedure set forth with specificity the grounds upon which a search warrant may be secured. Under the rules, the FDA would be required to show probable cause to the Court that property which is present in a plant is "designed or intended for use or which is or has been used as the means of commiting a criminal offense." This would appear to be a difficult undertaking. This was pointed out by the FDA in a statement by the then Commissioner to the House of Representatives Committee on Interstate and Foreign Commerce in 1953. The Commissioner stated in part:

> The General Counsel's Office of the Department advises us that there are clear congressional precedents for inspections of the type we proposed without the necessity of a search warrant. For example, 26 United States Code 3601, originally enacted a great many years ago, authorizes internal revenue inspectors to enter any establishment where articles subject to tax are made, produced, or kept, for the purpose of examining such articles.
>
> Examples from legislation administered by the Department of Health, Education, and Welfare are sections 351(c) and 361(a) of the Public Health Service Act. Section 351(c) authorizes any officer, agent, or employee of the Department, who has been authorized for the purpose by the Secretary, to enter and inspect during all reasonable hours any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, or analogous product for sale, barter, or exchange in the District of Columbia, or to be transported in interstate or foreign commerce. Section 361(a) authorizes the Surgeon General to provide for inspection in the enforcement of the interstate and foreign quarantine regulations.
>
> A requirement that inspection be conditioned on our obtaining a search warrant would largely defeat the purpose of inspection. The delay incident to this procedure would thwart enforcement. And in many instances we would be unable to make the "probable cause" showing necessary to have the warrant issued. Rule 41, Federal Rules of Criminal Procedure, would require us to show that the factory, establishment, or vehicle sought to be inspected was "designed or intended for use or . . . is or has been used as the means of committing a criminal offense" before we could obtain a search warrant. Since manufacture of misbranded or adulterated drugs is not itself ordinarily an offense under the Federal Food, Drug, and Cosmetic Act, such a showing would be a practical impossibility in most cases.

Permission to Inspect

In my opinion one cannot be compelled, as a matter of law, to permit an inspection of many weeks or months. What is sought by the government, therefore, is inspection for which permission is voluntarily granted. As a matter of policy, it appears to me that an intensified inspection may serve an extremely useful and educational purpose in most instances and, as long as it is conducted in a reasonable manner, should be permitted. **[The End]**

Now Available For the First Time . . .

NEW RULES ON CONSUMER CREDIT PROTECTION

More than seven years in the making, the federal truth-in-lending rules will have a major impact on the consumer-finance field. This powerful new legislation in the form of a federal Truth-in-Lending Act, and a Uniform Consumer Credit Code proposed for state enactment, provides for comprehensive control of nearly all aspects of consumer credit.

What does this new legislation mean? What are its "whys" and "wherefores"?

You'll find the answers in this handy new CCH volume which brings together for the first time the pertinent law, regulations, code draft and official Commissioners' Comments.

Provided are full details on how the new federal legislation affects retailers and lenders. The safeguards of the Code for consumer and creditor alike are covered fully. CCH's thorough, expert explanations help in answering the many and varied questions concerning consumer credit disclosure requirements. Tables of Contents for laws and regulations and a topical index are also included.

Almost everyone extending consumer credit, including their advertisers, is subject to the disclosure requirements of the law and of Regulation Z, prescribed by the Federal Reserve Board. Whatever your interest—buyer or seller, borrower or lender—this authoritative new CCH volume will serve as an invaluable primary source of information and easy-to-use reference on these unfamiliar new rules.

Completely up-to-date as of February 10, 1969, CCH's NEW RULES ON CONSUMER CREDIT PROTECTION offers the last word, the latest answers on federal and proposed state rules regulating consumer credit. In all, 440 pages, topical index, table of contents, 6" x 9", perfect bound, heavy paper cover.

Order Your Copies Now

To receive your copies promptly, just use the handy order form attached. Yours will be one of the first-press copies.

COMMERCE CLEARING HOUSE, INC.

PUBLISHERS of TOPICAL LAW REPORTS

420 LEXINGTON AVE. NEW YORK 10017 | 4025 W. PETERSON AVE. CHICAGO 60646 | 425 13TH STREET, N. W. WASHINGTON 20004

FOOD DRUG COSMETIC
LAW JOURNAL

PUBLISHED BY
COMMERCE CLEARING HOUSE, INC.
PUBLISHERS of TOPICAL LAW REPORTS
4025 W. PETERSON AVE., CHICAGO, ILL. 60646
RETURN REQUESTED

SECOND CLASS POSTAGE PAID
AT CHICAGO, ILLINOIS AND
AT ADDITIONAL MAILING OFFICES

A COMMERCE CLEARING HOUSE PUBLICATION